

**Volume II of IX (Appx597-Appx22999)
No. 2024-1285**

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

NON-CONFIDENTIAL JOINT APPENDIX

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CERTIFICATE OF SERVICE

CONFIDENTIAL MATERIAL OMITTED

The material omitted from Appx9; Appx36; Appx41-44; Appx46-48; Appx108; Appx119; Appx121-122; Appx150-151; Appx153-154; Appx156-158; Appx187-190; Appx192-194; Appx196; Appx198; Appx218; Appx220-222; Appx265-276; Appx373; Appx13067-13069; Appx21846; Appx22790; Appx22954; Appx22956-22958; Appx22985; Appx22990; Appx23139; Appx23166; Appx23171-23174; Appx23238; Appx23249; Appx23251-23252; Appx23280-23281; Appx23283-23284; Appx23286-23288; Appx23317-23320; Appx23322-Appx23323; Appx23326; Appx23328; Appx23348; Appx23350-23352; Appx23395-23406; Appx23656; Appx23658; Appx23681-23682; 23688; Appx23791; Appx24147-24148; Appx40795-40798; Appx40996-40999; Appx41019-41026; Appx41029-41030; Appx41058-41062; Appx41077-41080; Appx41094-41097; Appx41108-41110; Appx51900-51924; Appx52602-52606; Appx52609; Appx52642-52645; Appx52791-52795; Appx52822-52824; Appx52911-52912; Appx52939-52941; Appx52980-52982; Appx53016-53019; Appx60425-60431; Appx60432-60434; Appx70322-70355; Appx70774; Appx70781-70783; and Appx70841-70876 contains Apple's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx4579 and Appx53459-53461 contains competitively sensitive information regarding confidential agreements; the material omitted from Appx23439; Appx23441-23446; Appx23448; Appx23450-23453; Appx23455-23458; Appx23462; Appx23617; Appx23621; Appx23659-23665; Appx25251; Appx40483; Appx40582-40584; Appx40600-40601; Appx40605; Appx40652-40655; Appx40658-40662; Appx53491; Appx53492; Appx53497; Appx53499; Appx53503; Appx53506; Appx65064-65075; Appx65075; Appx65104-65105; Appx65315; Appx65321-65232; and Appx71223-71244 contains Masimo's confidential competitively sensitive financial information subject to the Administrative Protective Order; the material omitted from Appx311-316; Appx23667-23674; Appx40579-40581; Appx40585-40599; Appx40602-40604; Appx40610-40614; and Appx40631-40633 contains Masimo's confidential competitively sensitive financial and manufacturing information subject to the Administrative Protective Order; the material omitted from Appx473-474; Appx62; and Appx23176-23178 contains Masimo's confidential competitively sensitive manufacturing information subject to the Administrative Protective Order; the material omitted from Appx13047; Appx14129-14140; Appx205-206; Appx211; Appx21848; Appx22282-22286; Appx23197; Appx23204; Appx23335-23336; Appx23341; Appx23408-23416; Appx23434-23436; Appx23454; Appx23642; Appx23644-23645; Appx23647-23649; Appx23685-23687; Appx23693-23697; Appx23704; Appx25253-25260; Appx278-286; Appx2809-

2852; Appx2923-2937; Appx304-306; Appx309; Appx3708; Appx3710-3711; Appx3718; Appx3722; Appx3725; Appx3727; Appx3732; Appx3733; Appx3735; Appx40229-40232; Appx40346-40371; Appx40407-40422; Appx40431-40434; Appx40438-40442; Appx40486-40494; Appx40495-40506; Appx40512-40521; Appx40525-40528; Appx40547-40555; Appx40560-40574; Appx40803-40822; Appx41217-41221; Appx41350-41356; Appx53070-53095; Appx53107-53151; Appx53222-53234; Appx53236-53252; Appx53256-53361; Appx53362-53365; Appx53813-53838; Appx53927-53941; Appx54064-54226; Appx54227-54266; Appx55229-55354; Appx55359-55376; Appx55386-55399; Appx57317-57324; Appx57394--57409; Appx57410-57412; Appx57615-57618; Appx60136-60153; Appx60184-60212; Appx65014-65019; Appx65022-65025; Appx65028-65037; Appx65040-65074; Appx65207; Appx65224; Appx65267-65268; Appx67; Appx6701-6703; Appx6705; Appx6732-6736; Appx6852-6854; Appx6937-6950; Appx70475; Appx70484-70491; Appx70504-70513; Appx70518-70559; Appx70610-70613; Appx70615-70617; Appx70619-70628; Appx70833-70835; Appx70948-70950; Appx70955-70956; and Appx74 contains Masimo's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx23707-23709; Appx318; Appx320-328; Appx40634; and Appx70592-70594 contains Masimo's confidential competitively sensitive product and financial information subject to the Administrative Protective Order; the material omitted from Appx176; Appx179; Appx22788-22789; and Appx22791 contains Masimo's confidential information detailing non-public patent prosecution subject to the Administrative Protective Order; the material omitted from Appx404-405; Appx457; Appx460-461; Appx464; Appx24103-24104; Appx25387; and Appx25389 contains Apple's confidential competitively sensitive financial and sales information subject to the Administrative Protective Order; the material omitted from Appx52602-52608 contains confidential competitively sensitive product of a third party.



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(12) **United States Patent**
Poeze et al.

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(54) **USER-WORN DEVICE FOR
NONINVASIVELY MEASURING A
PHYSIOLOGICAL PARAMETER OF A USER**

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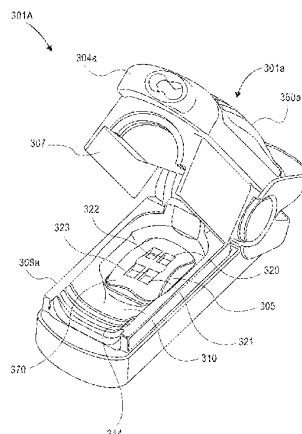
Primary Examiner — Chu Chuan Liu

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(57) **ABSTRACT**

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially linear substantially equal spaced geometry, a substantially linear substantially non-equal spaced geometry, and a substantially grid geometry.

30 Claims, 65 Drawing Sheets



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- No. 16/725,292, filed on Dec. 23, 2019, now Pat. No. 10,624,564, which is a continuation of application No. 16/534,949, filed on Aug. 7, 2019, now Pat. No. 10,588,553, which is a continuation of application No. 16/409,515, filed on May 10, 2019, now Pat. No. 10,376,191, which is a continuation of application No. 16/261,326, filed on Jan. 29, 2019, now Pat. No. 10,292,628, which is a continuation of application No. 16/212,537, filed on Dec. 6, 2018, now Pat. No. 10,258,266, which is a division of application No. 14/981,290, filed on Dec. 28, 2015, now Pat. No. 10,335,068, which is a continuation of application No. 12/829,352, filed on Jul. 1, 2010, now Pat. No. 9,277,880, which is a continuation of application No. 12/534,827, filed on Aug. 3, 2009, now abandoned, and a continuation-in-part of application No. 12/497,528, filed on Jul. 2, 2009, now Pat. No. 8,577,431, which is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516, said application No. 12/829,352 is a continuation-in-part of application No. 12/497,523, filed on Jul. 2, 2009, now Pat. No. 8,437,825, and a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516.
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See application file for complete search history.
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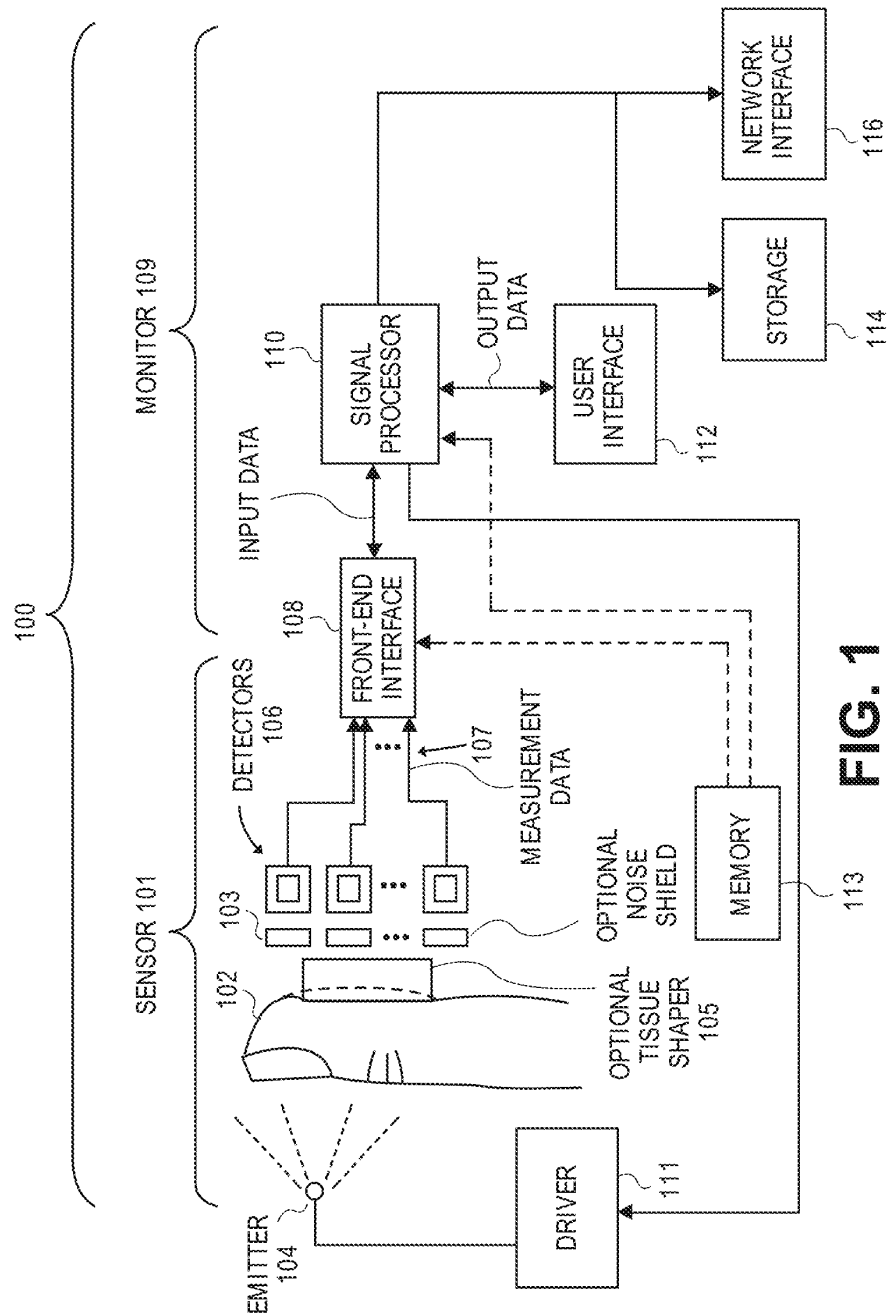


FIG. 1

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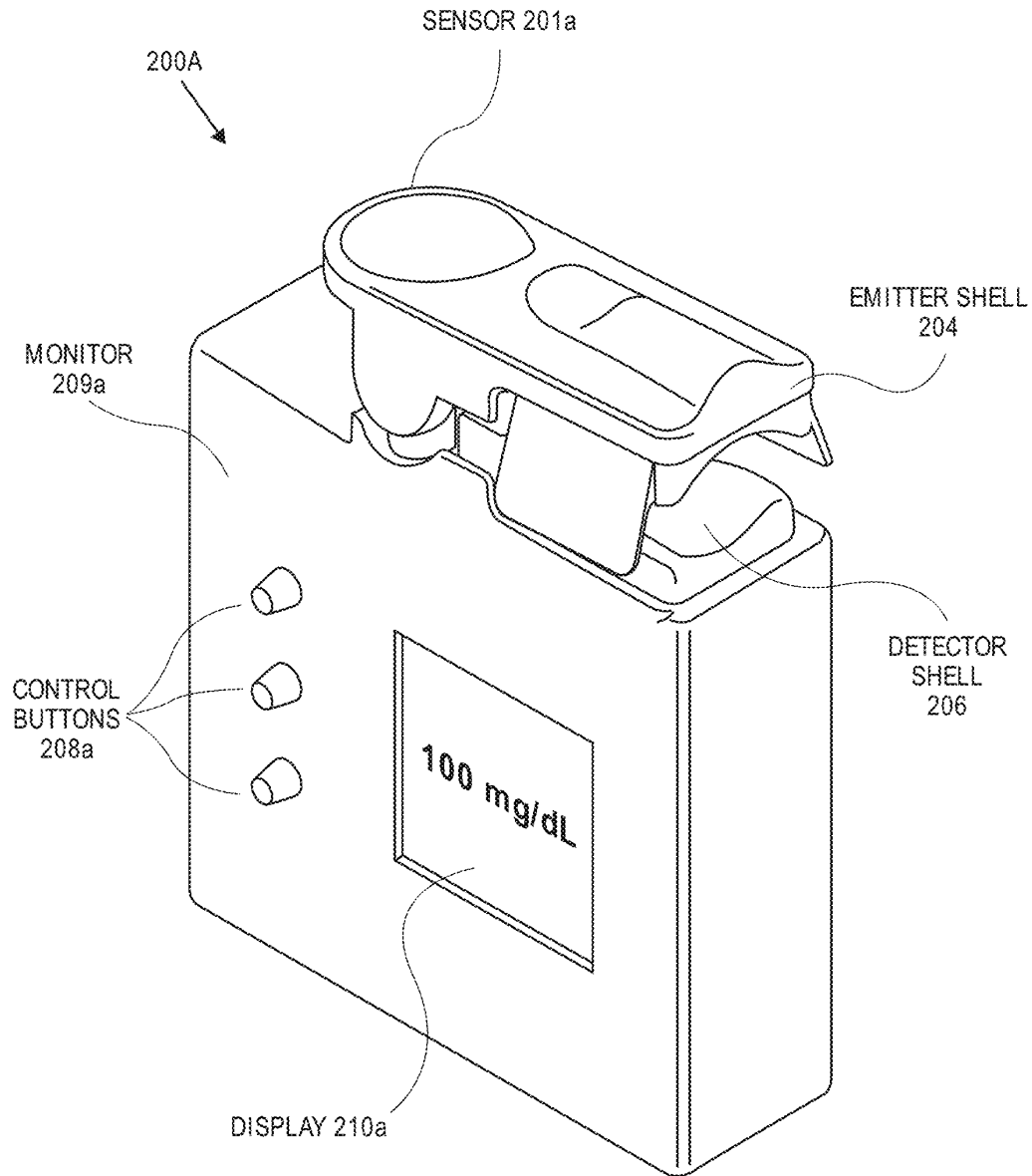


FIG. 2A

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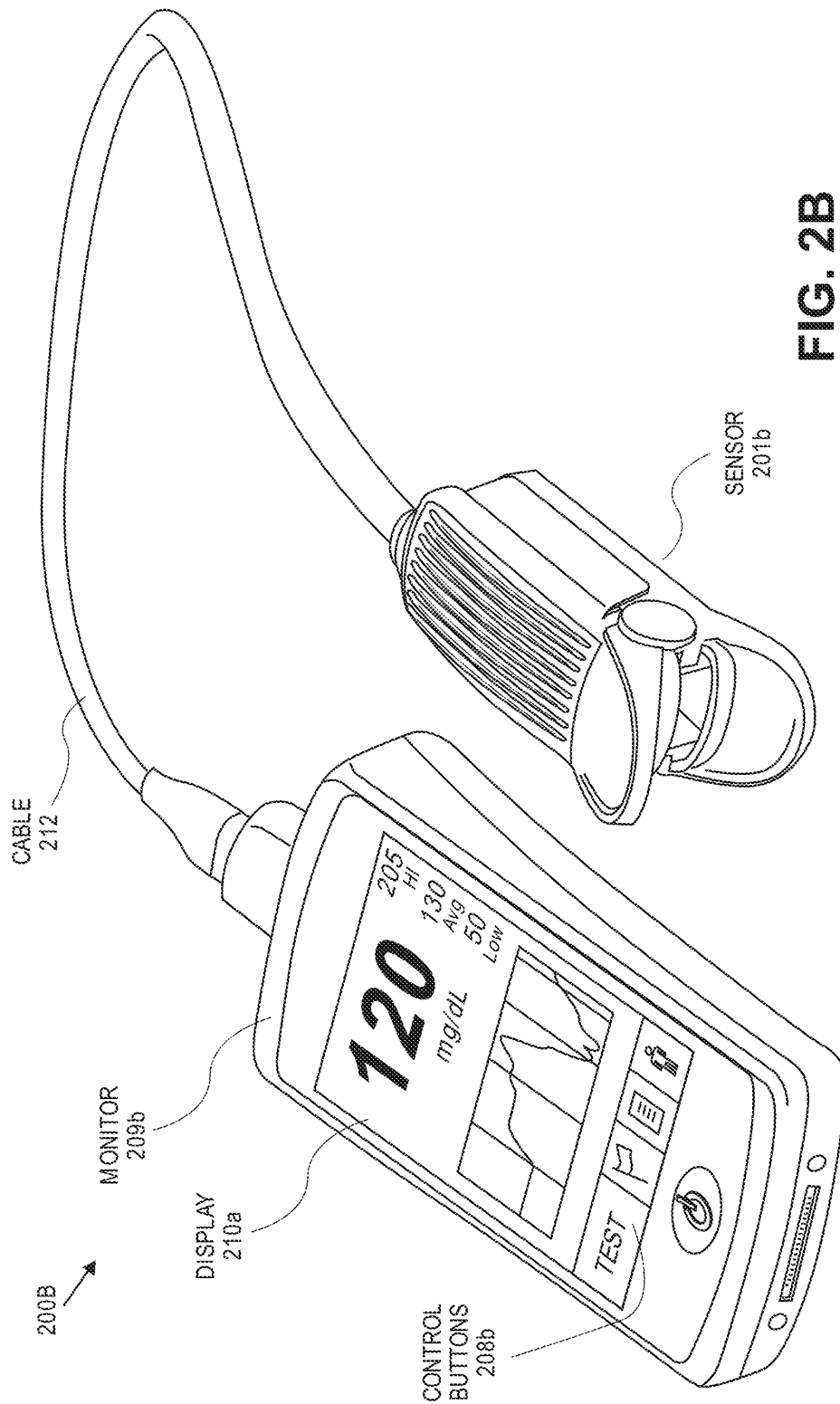


FIG. 2B

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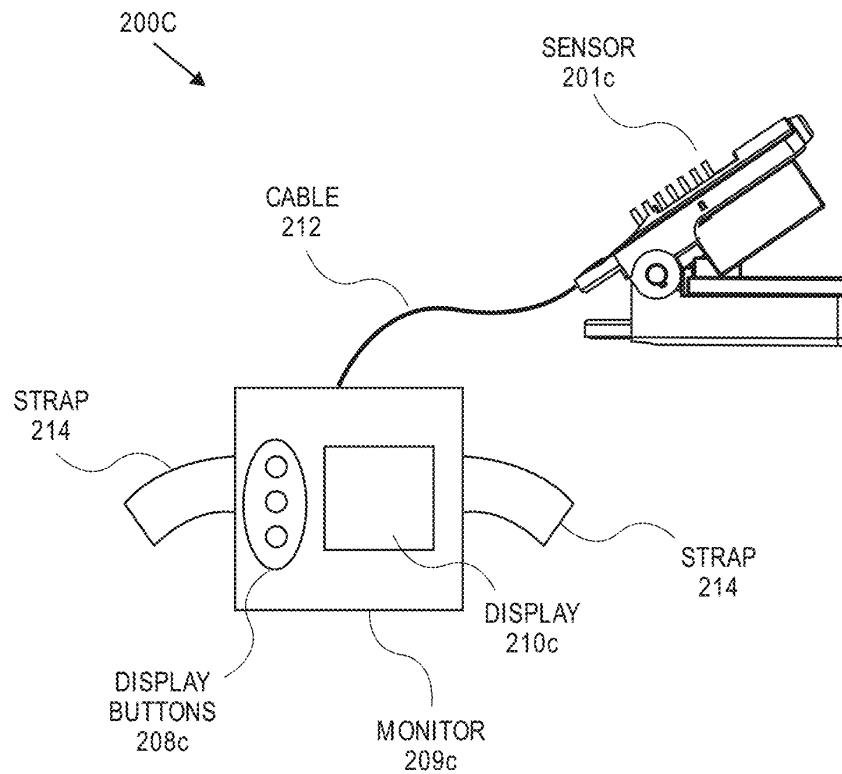


FIG. 2C

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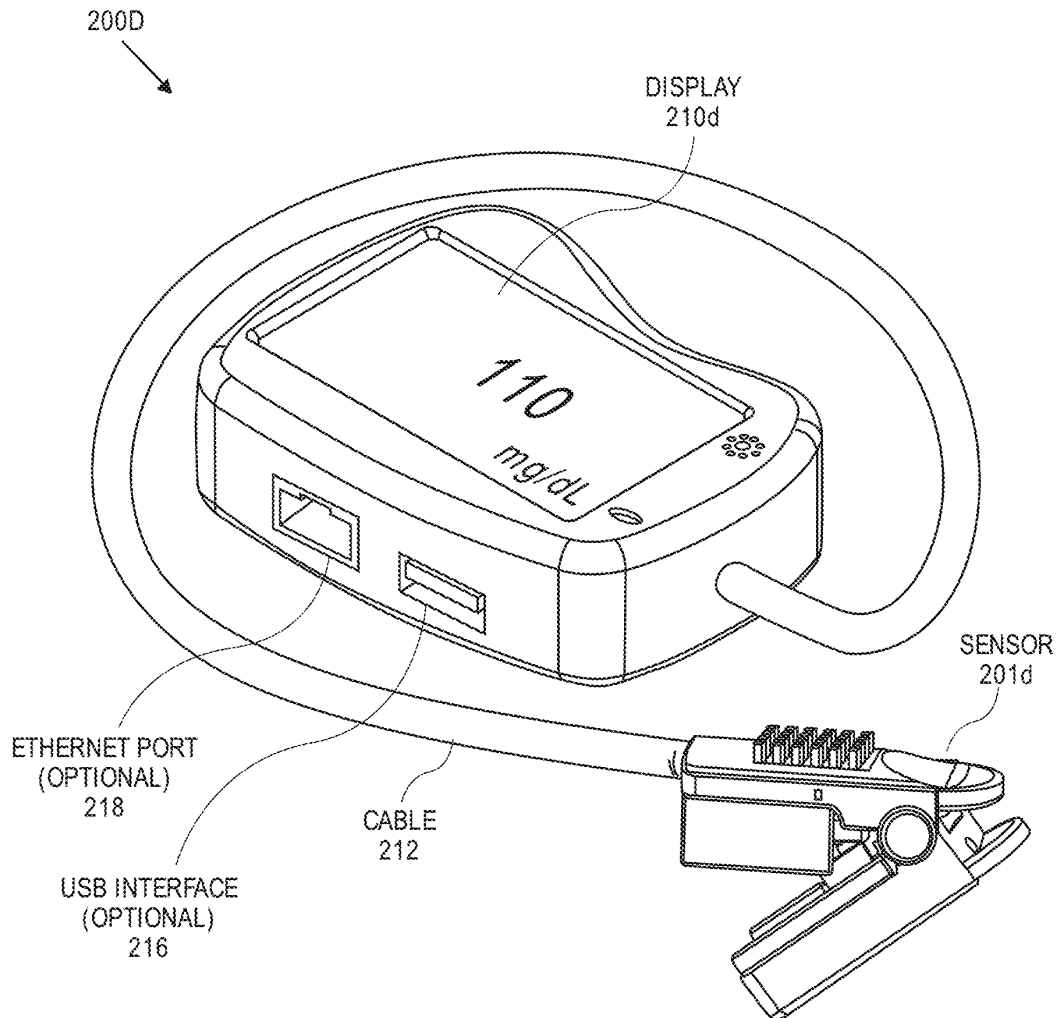


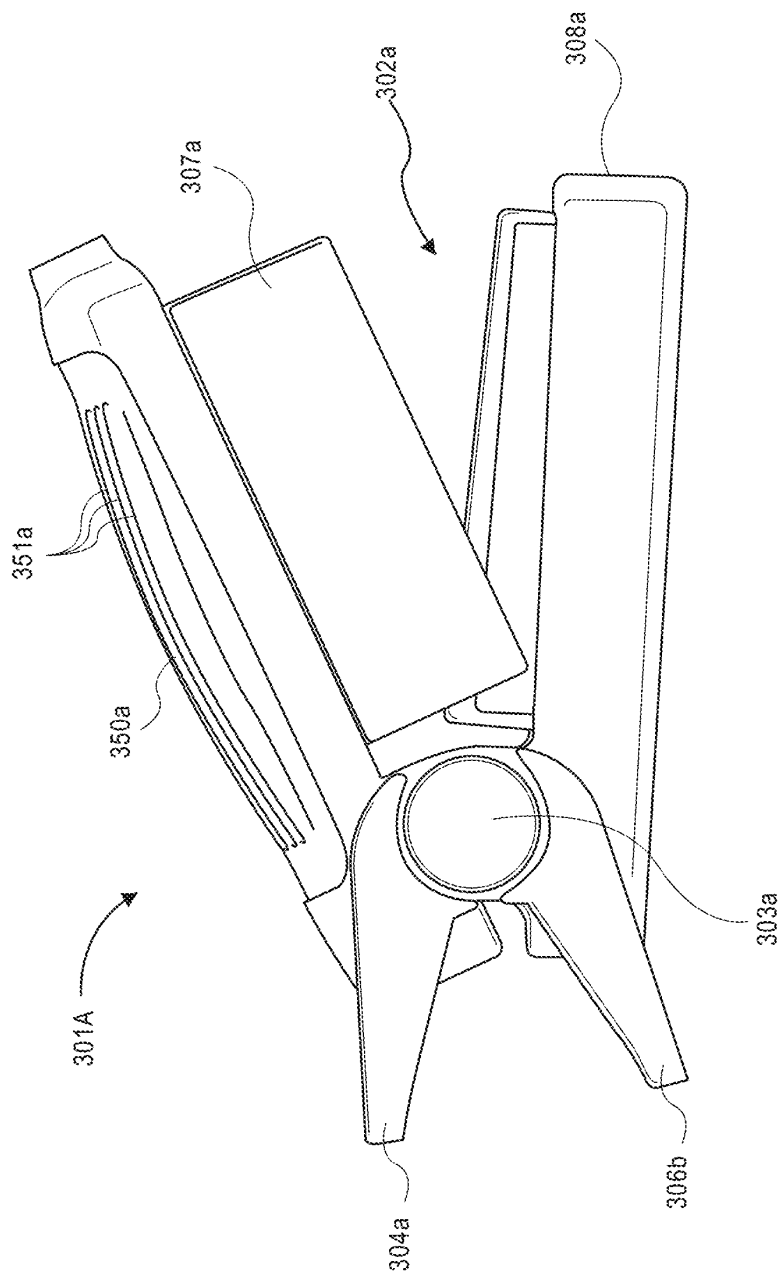
FIG. 2D

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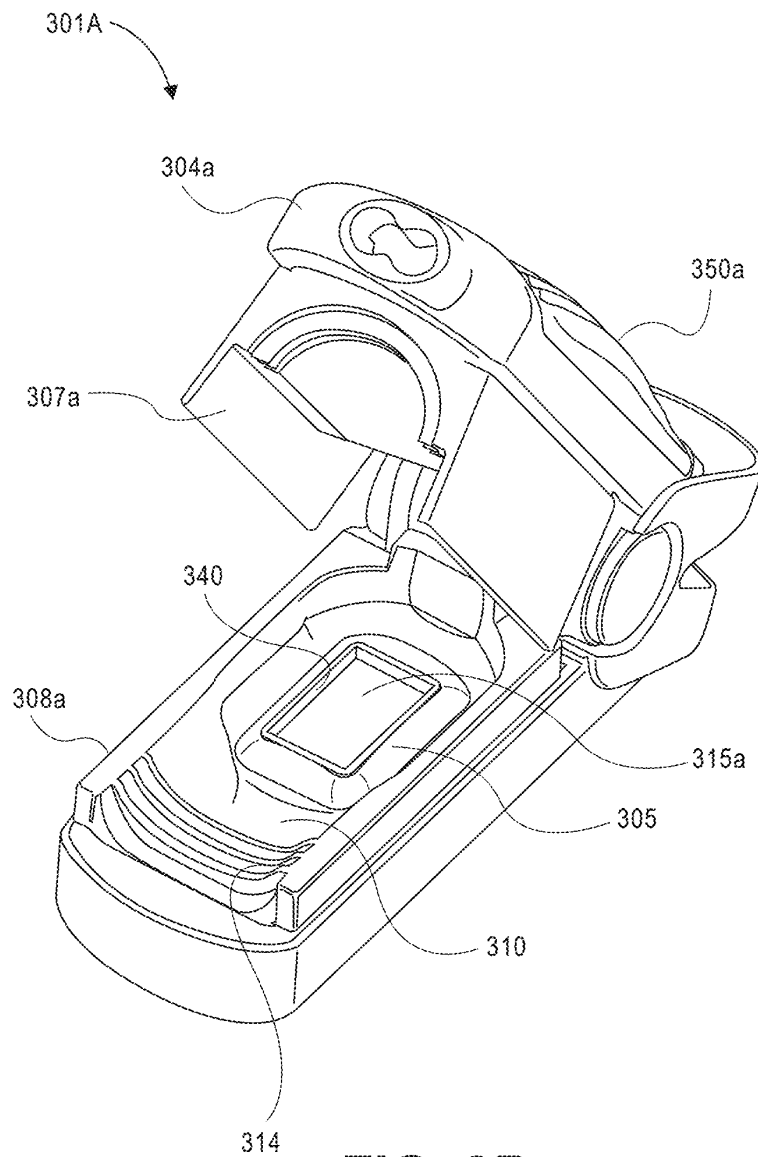


FIG. 3B

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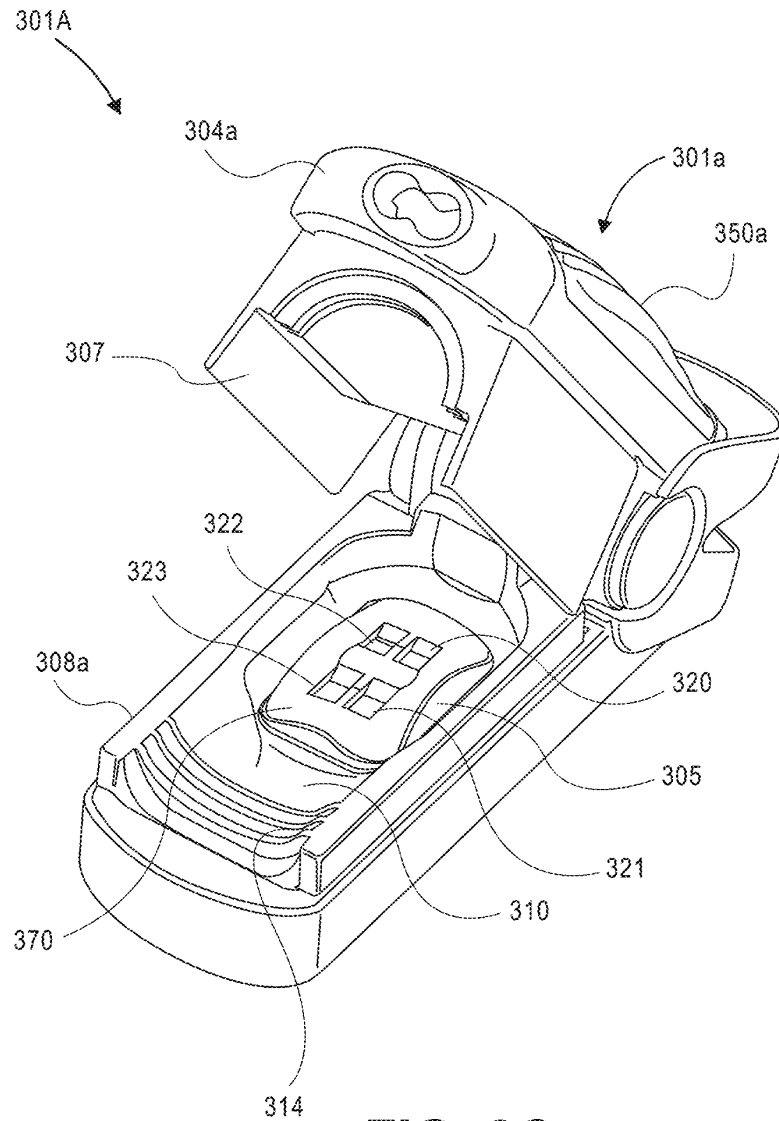


FIG. 3C

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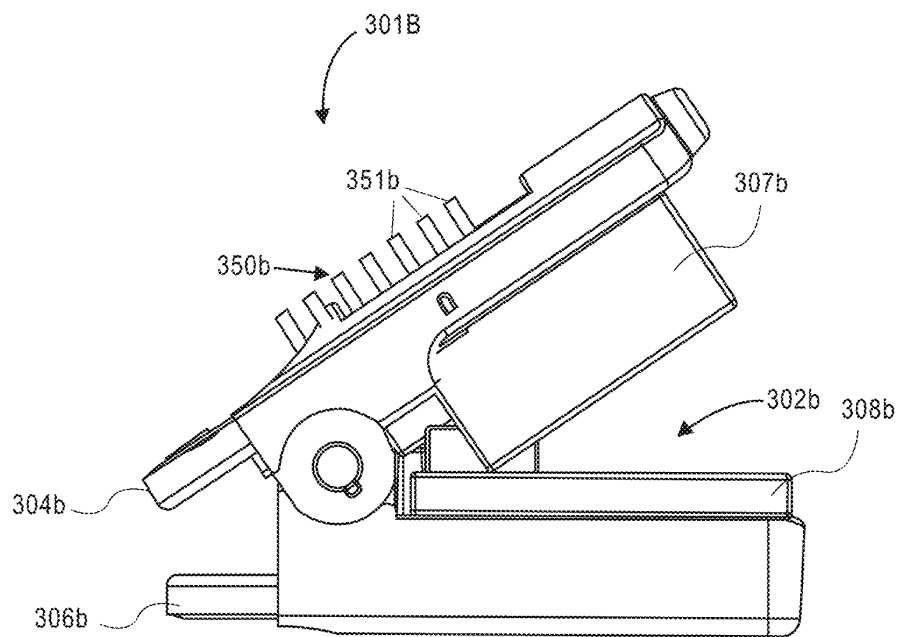


FIG. 3D

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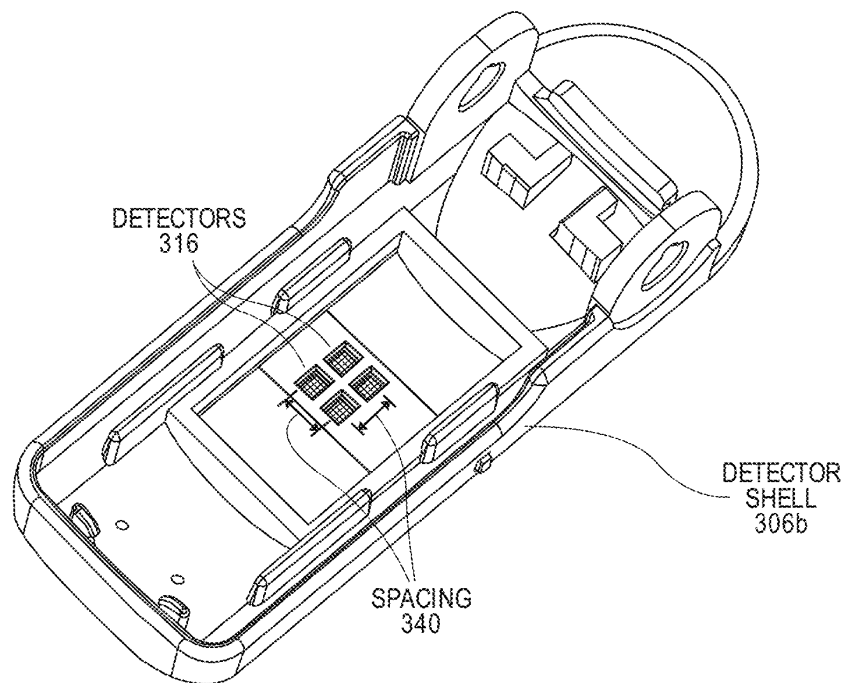


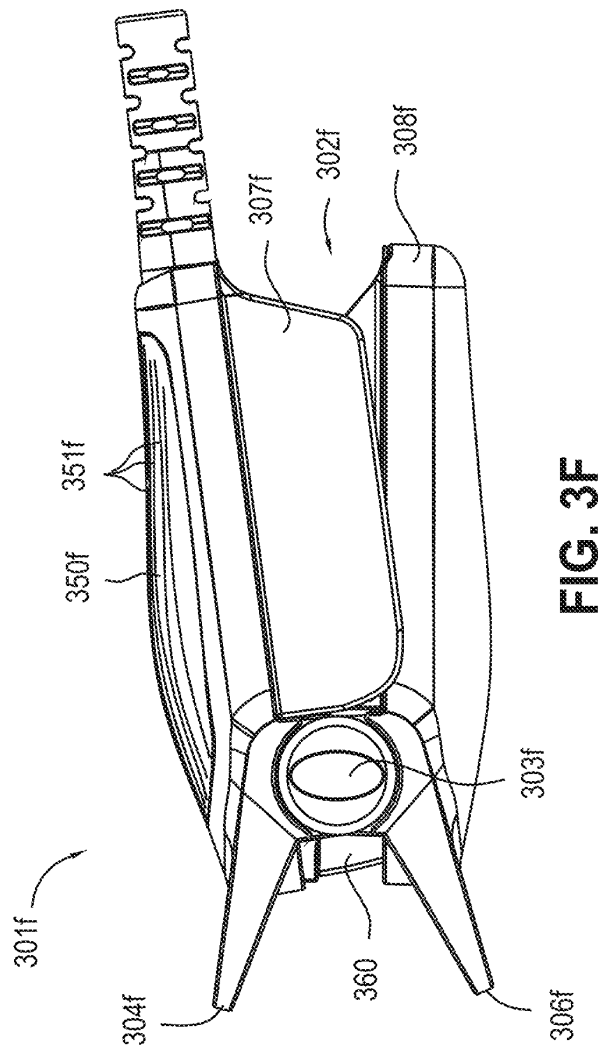
FIG. 3E

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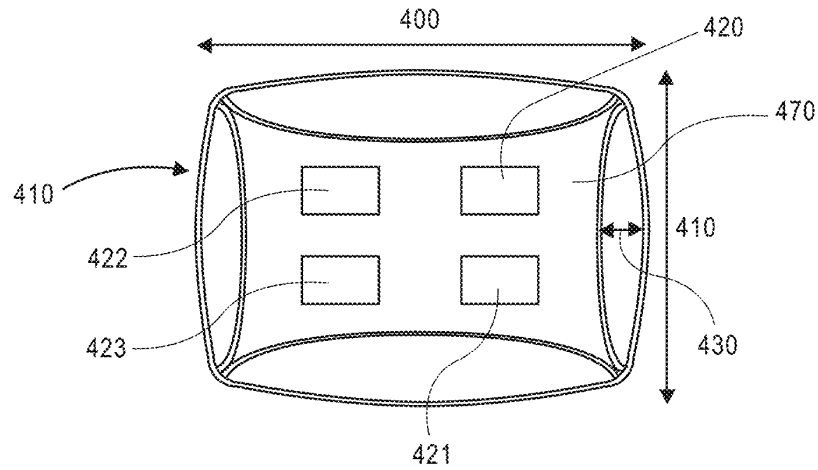


FIG. 4A

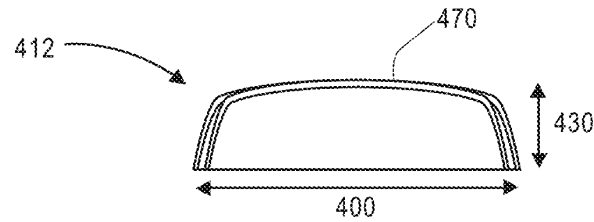


FIG. 4B

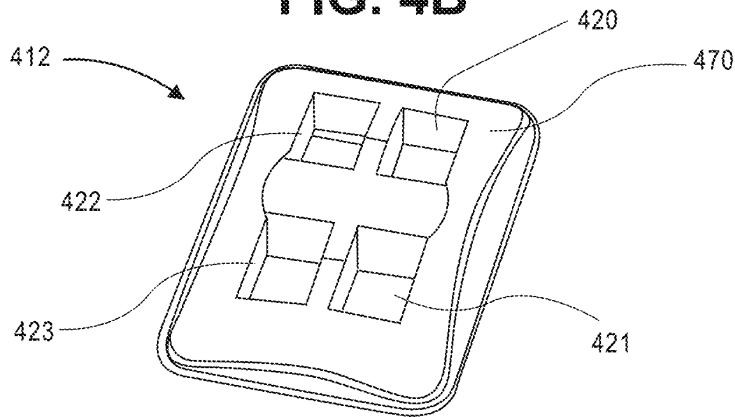


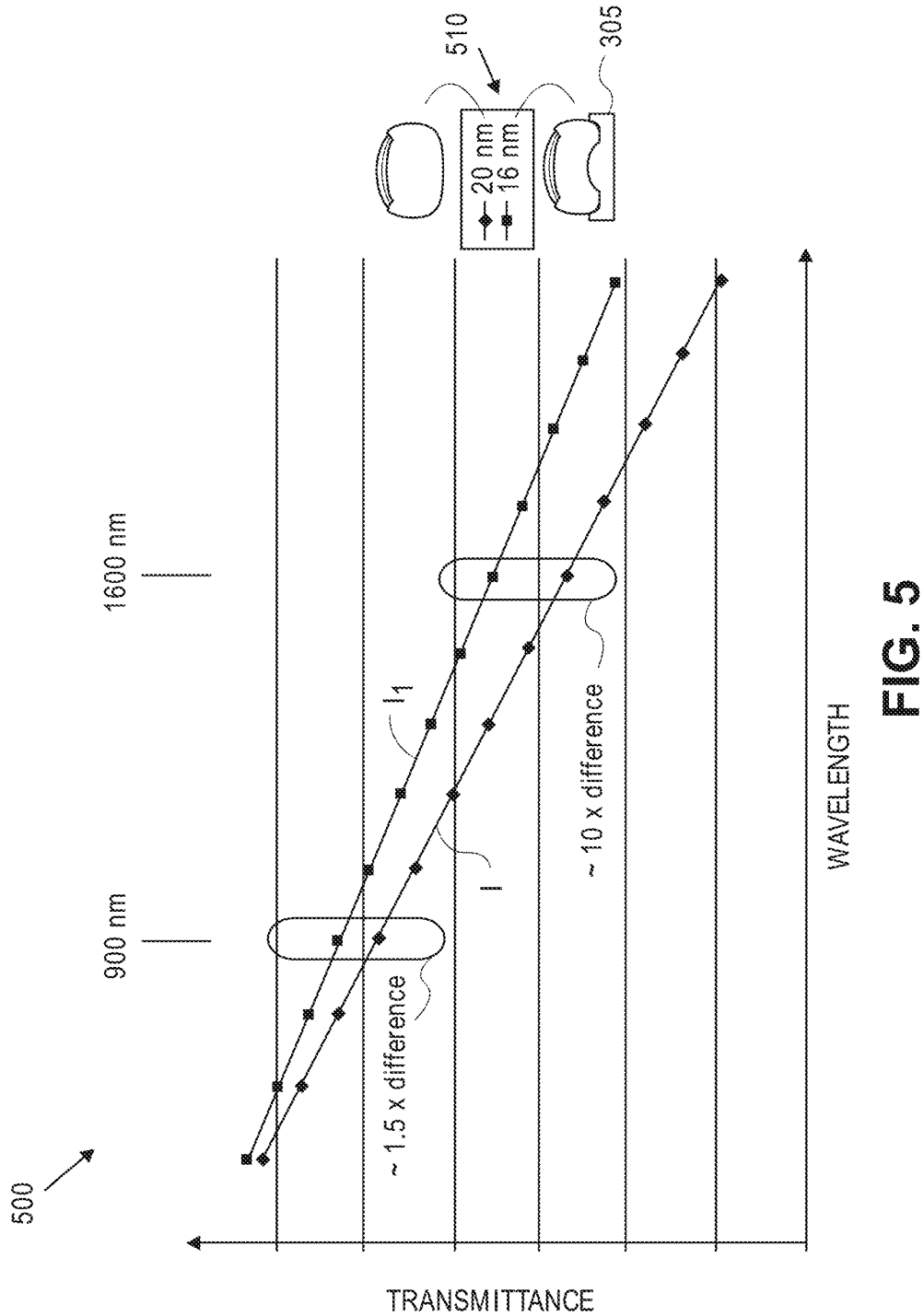
FIG. 4C

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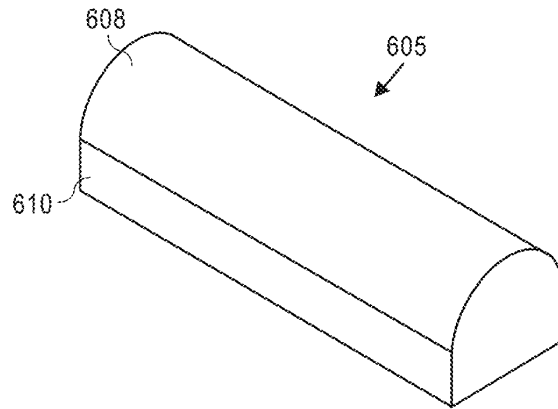


FIG. 6A

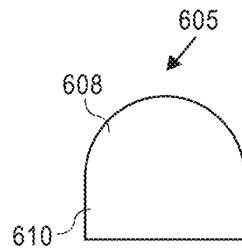


FIG. 6B

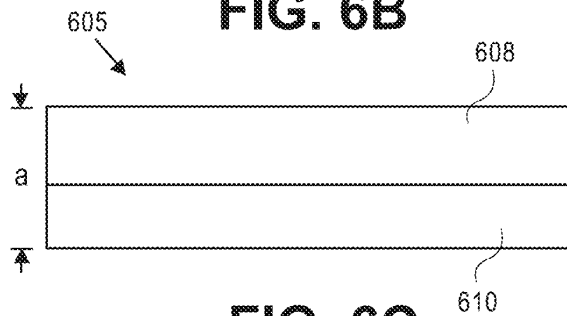


FIG. 6C



FIG. 6D

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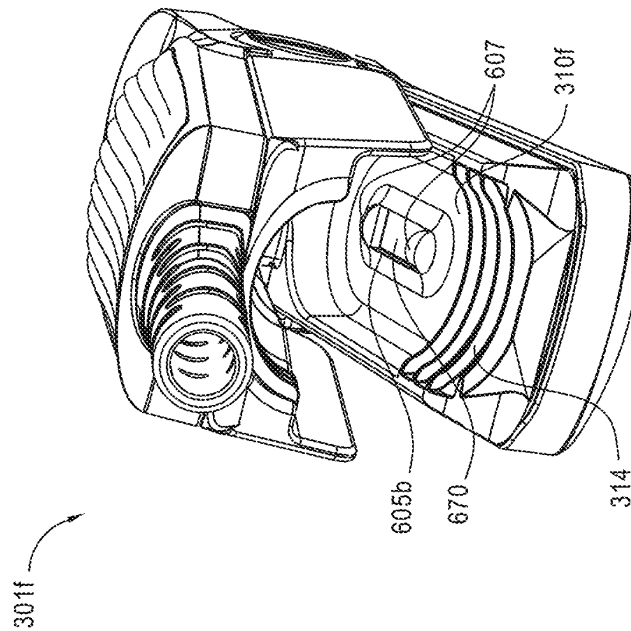


FIG. 6E

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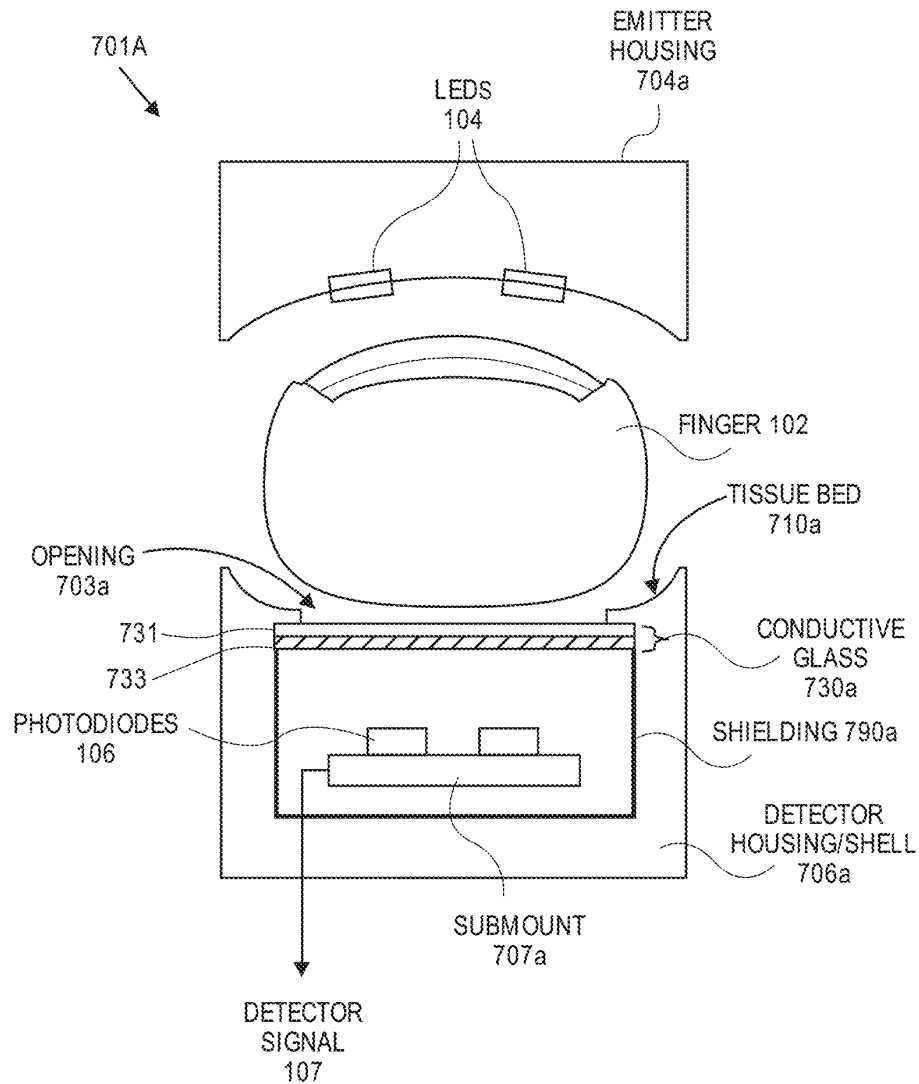


FIG. 7A

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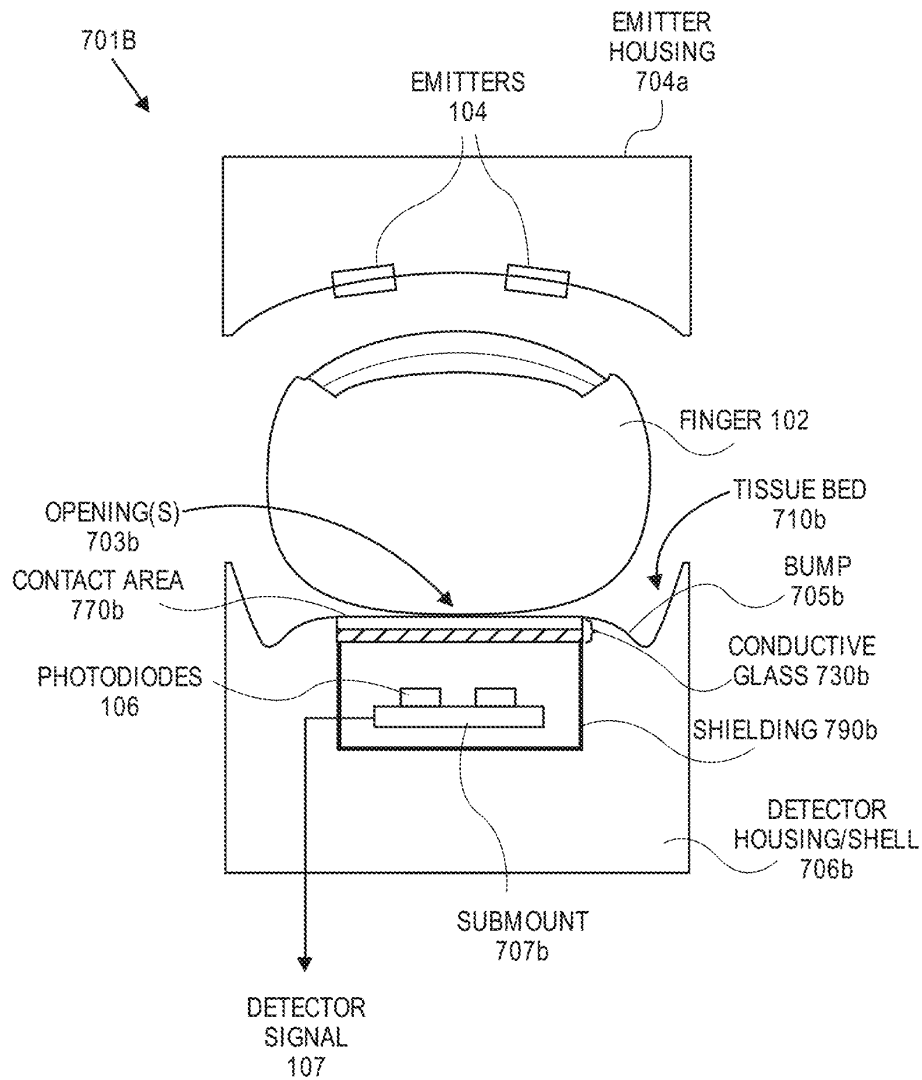


FIG. 7B

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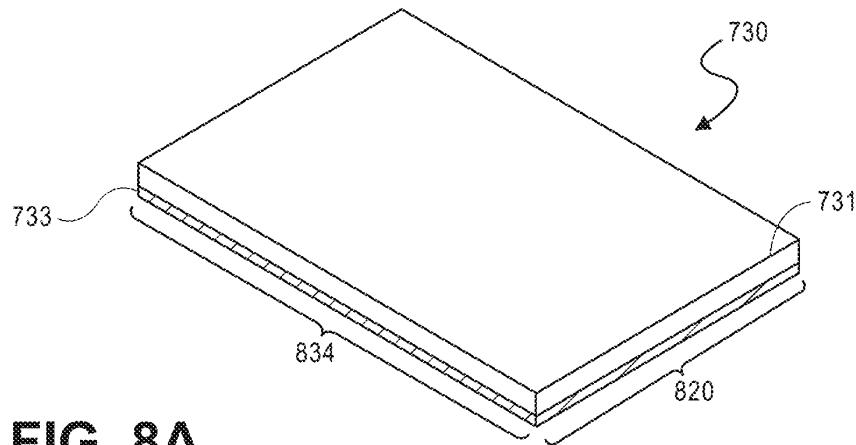


FIG. 8A

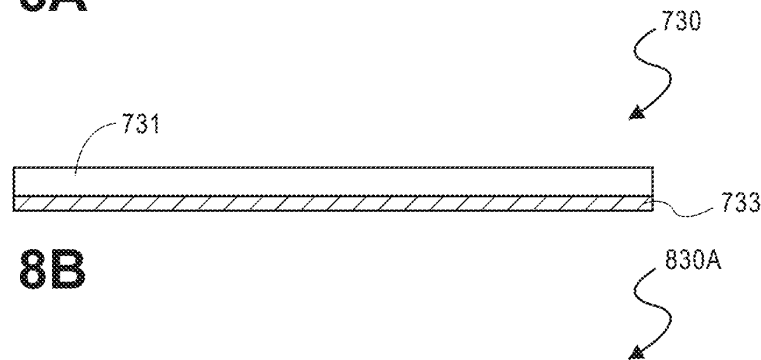


FIG. 8B

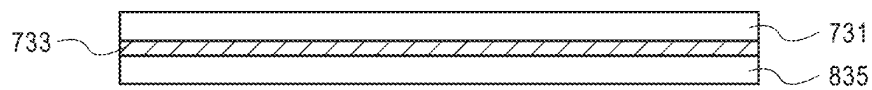


FIG. 8C

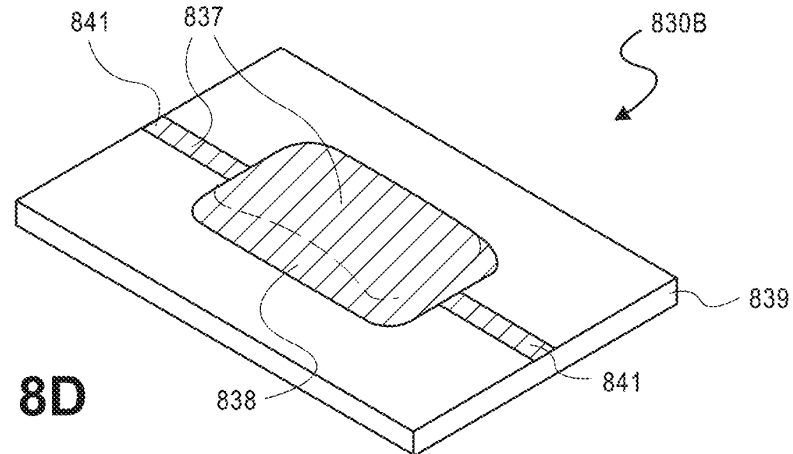


FIG. 8D

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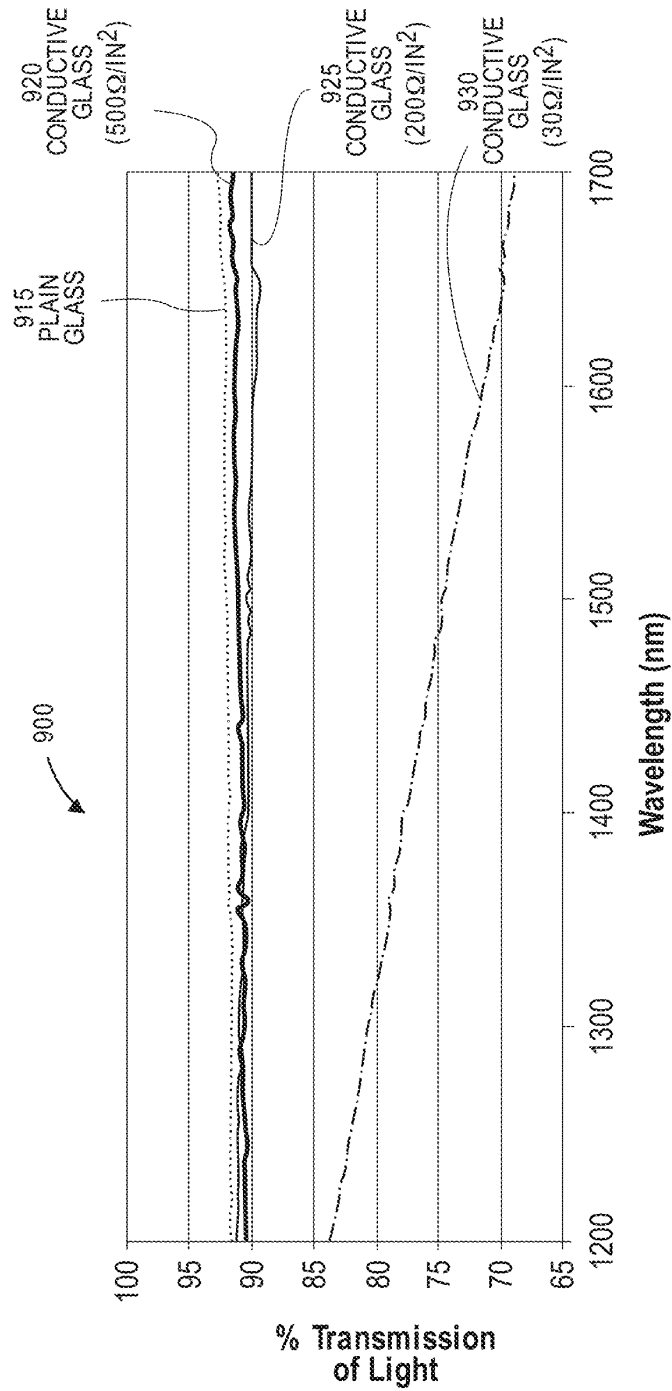


FIG. 9

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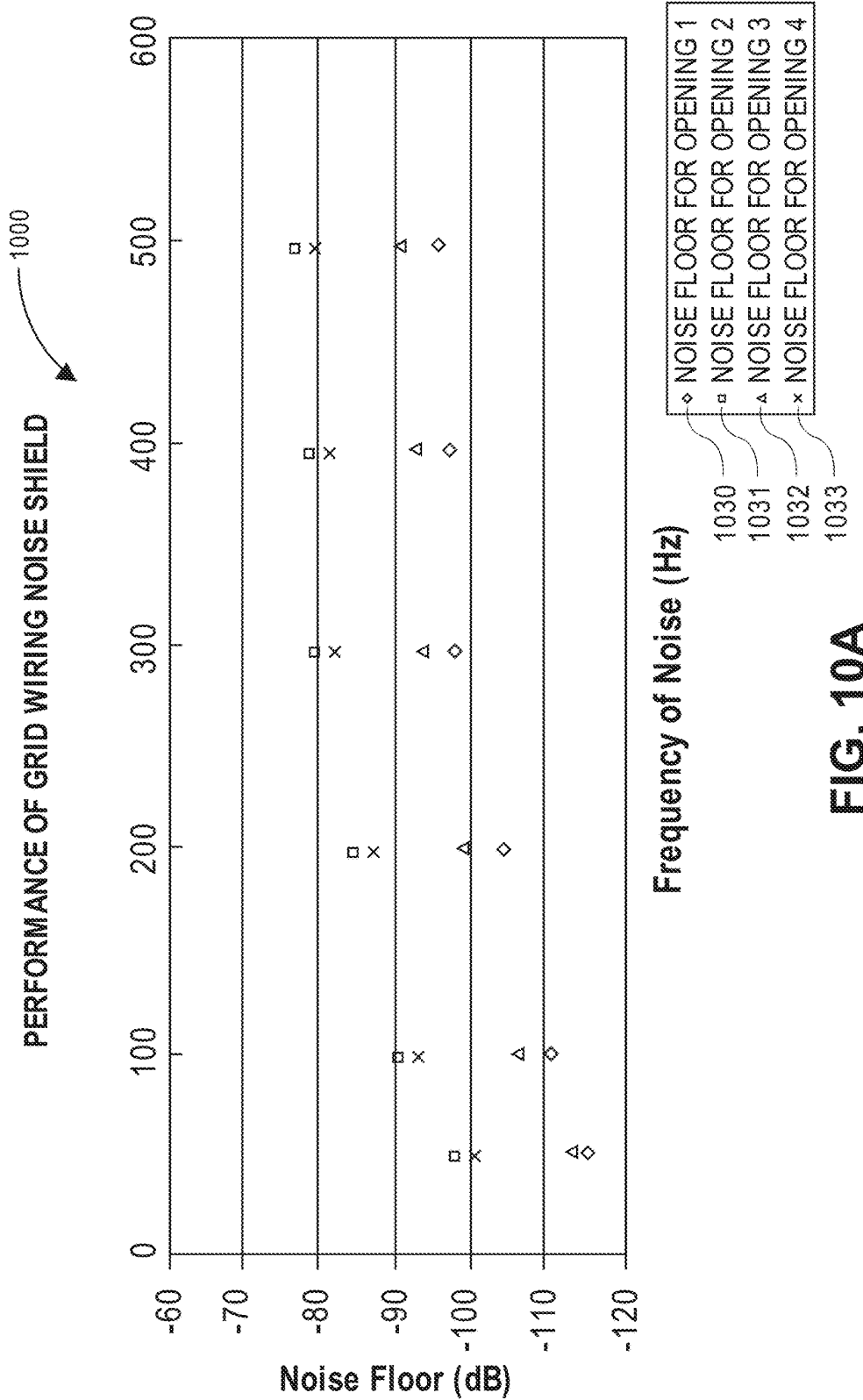


FIG. 10A

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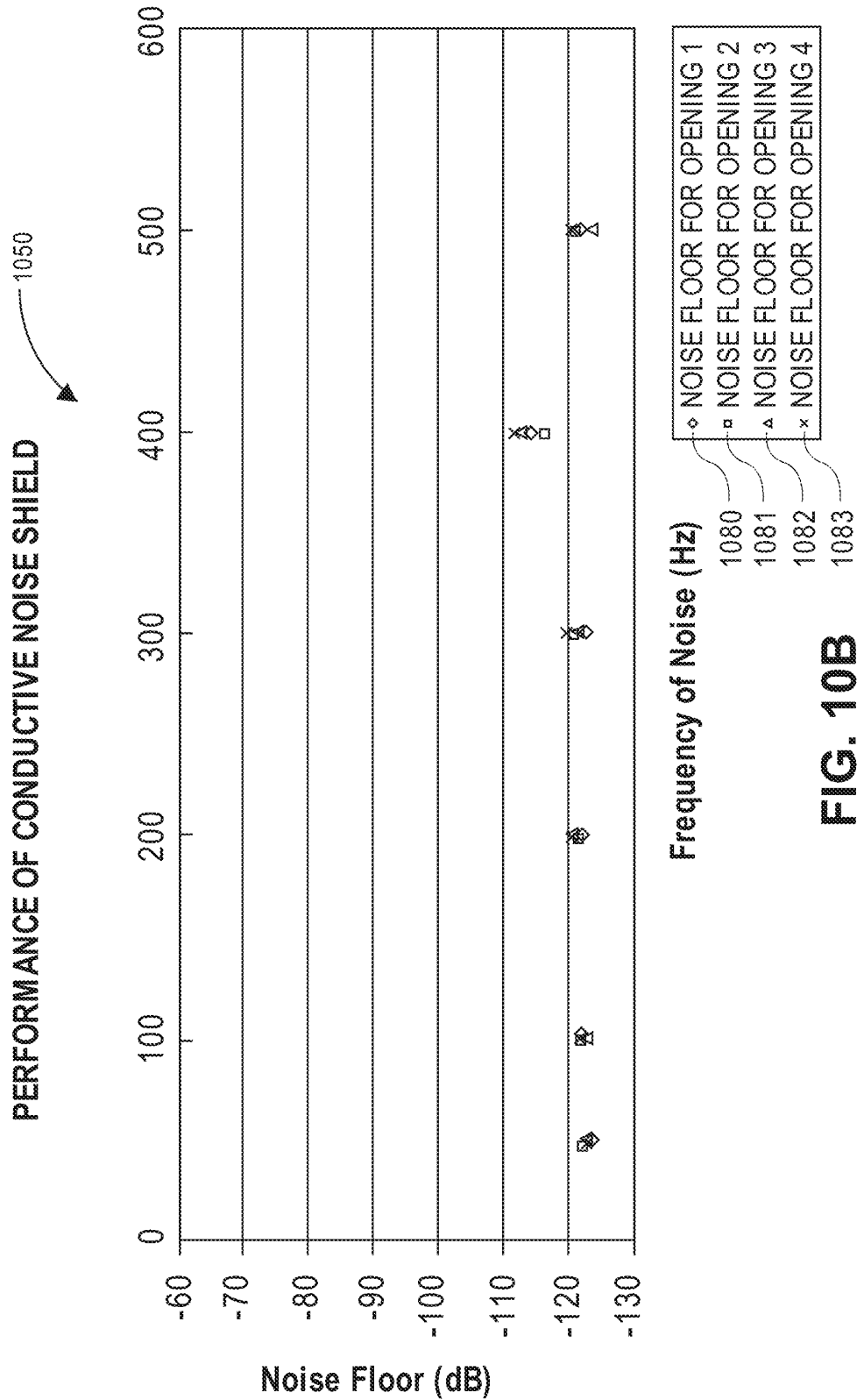


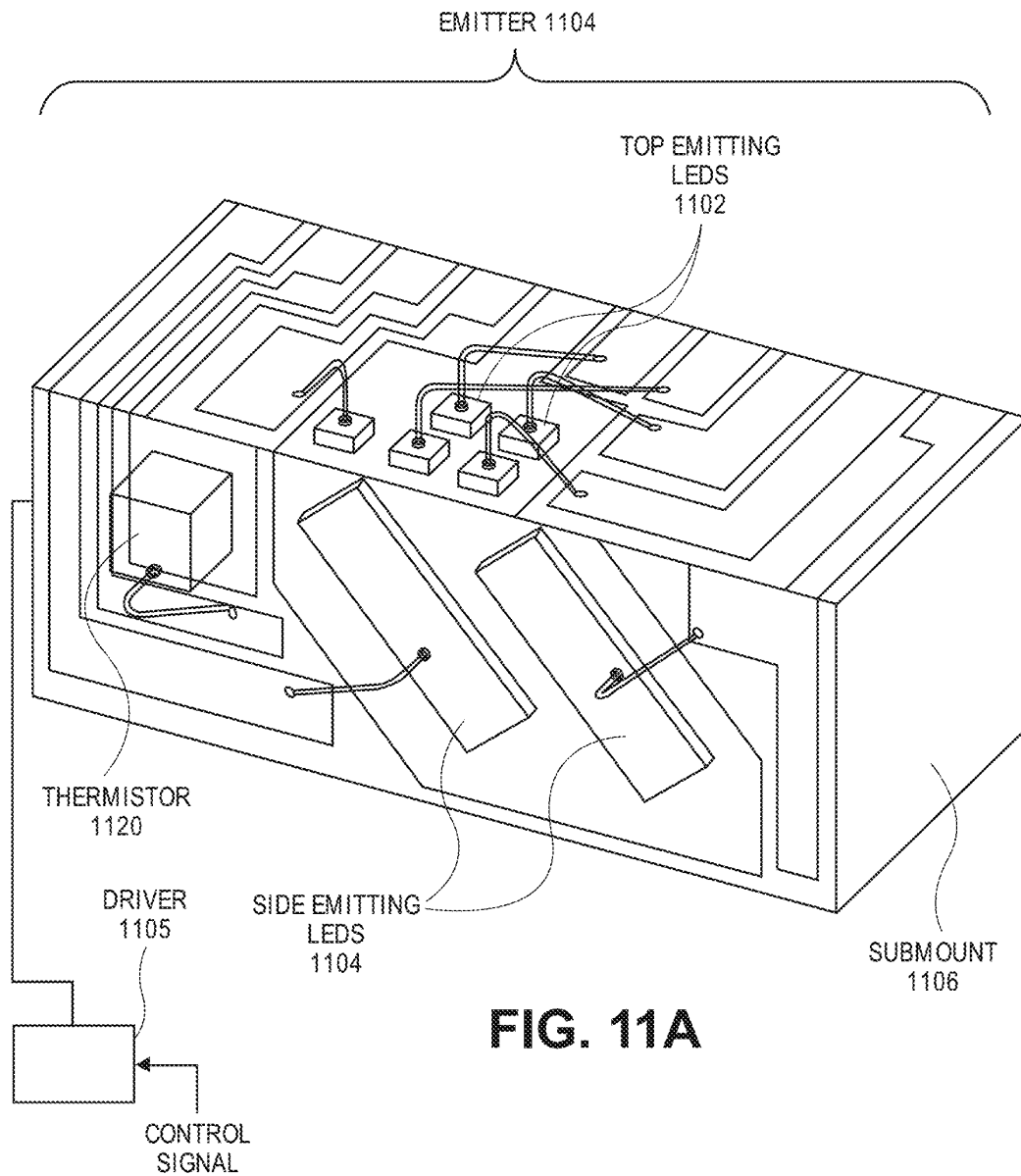
FIG. 10B

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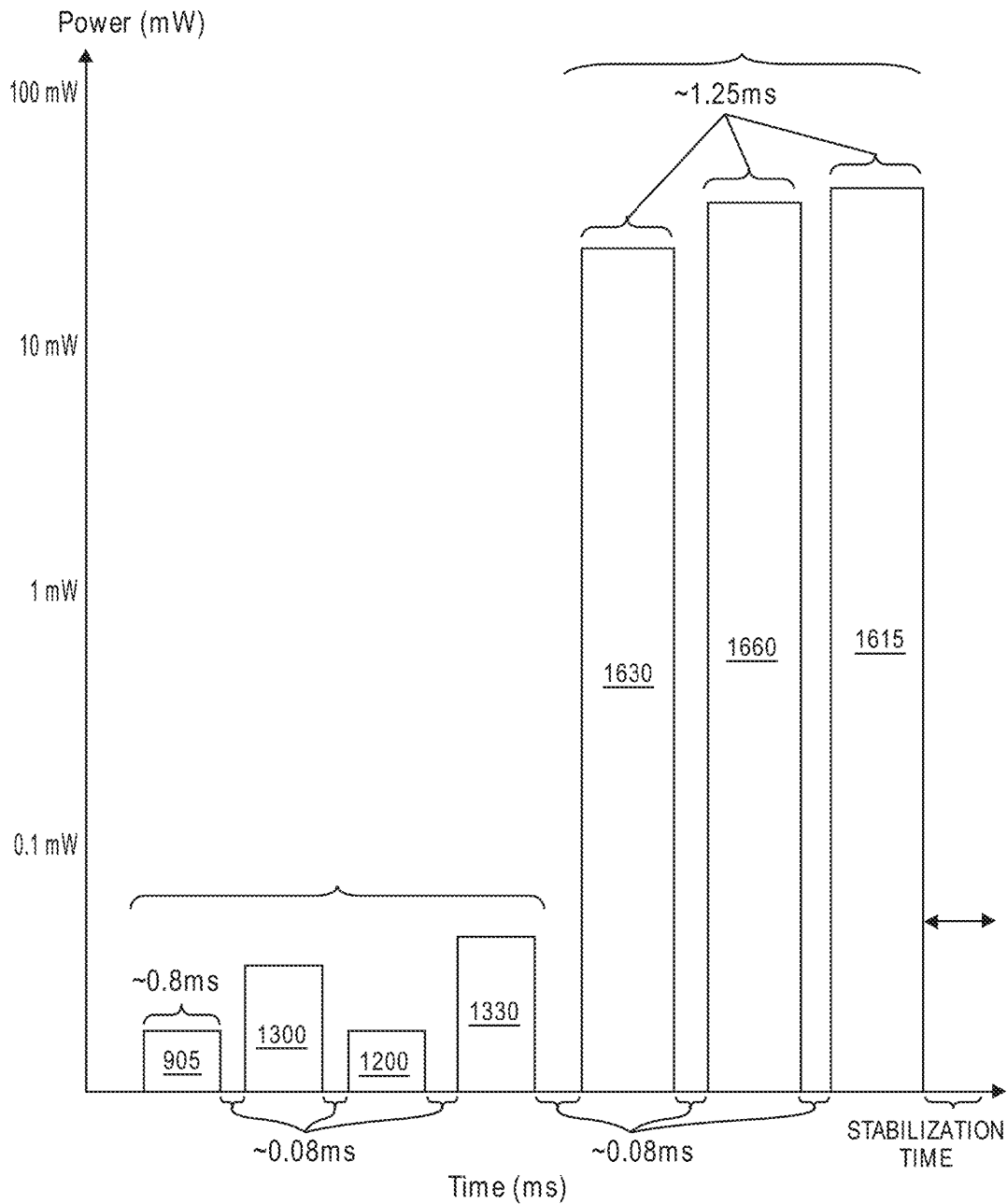


FIG. 11B

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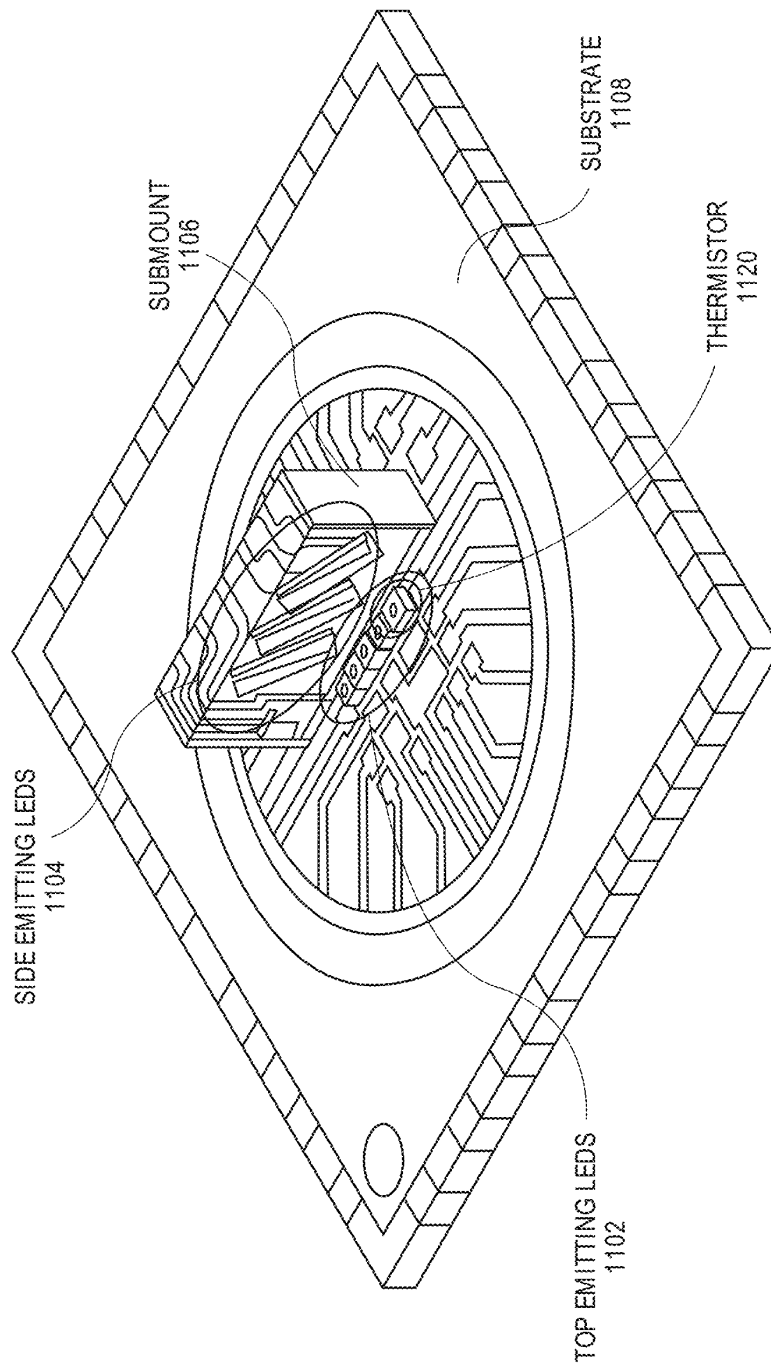


FIG. 11C

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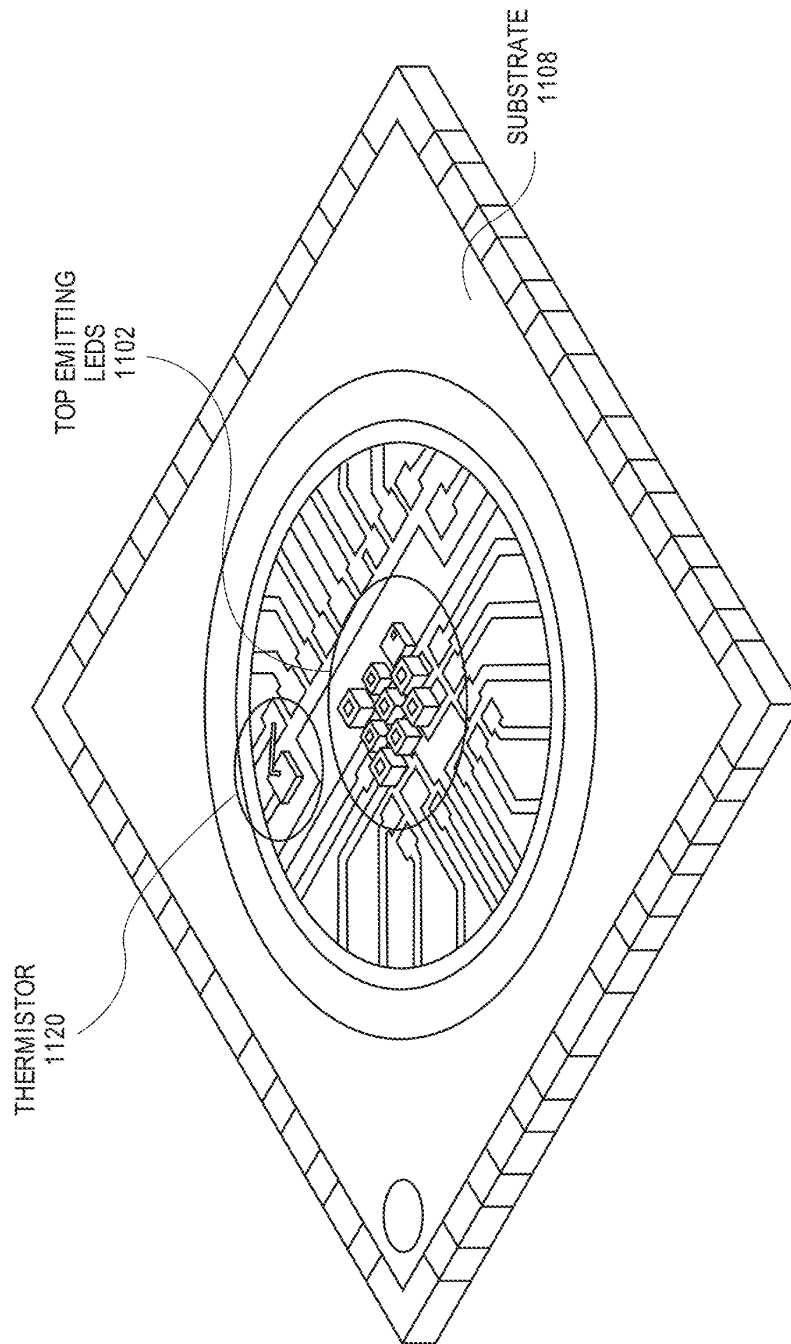


FIG. 11D

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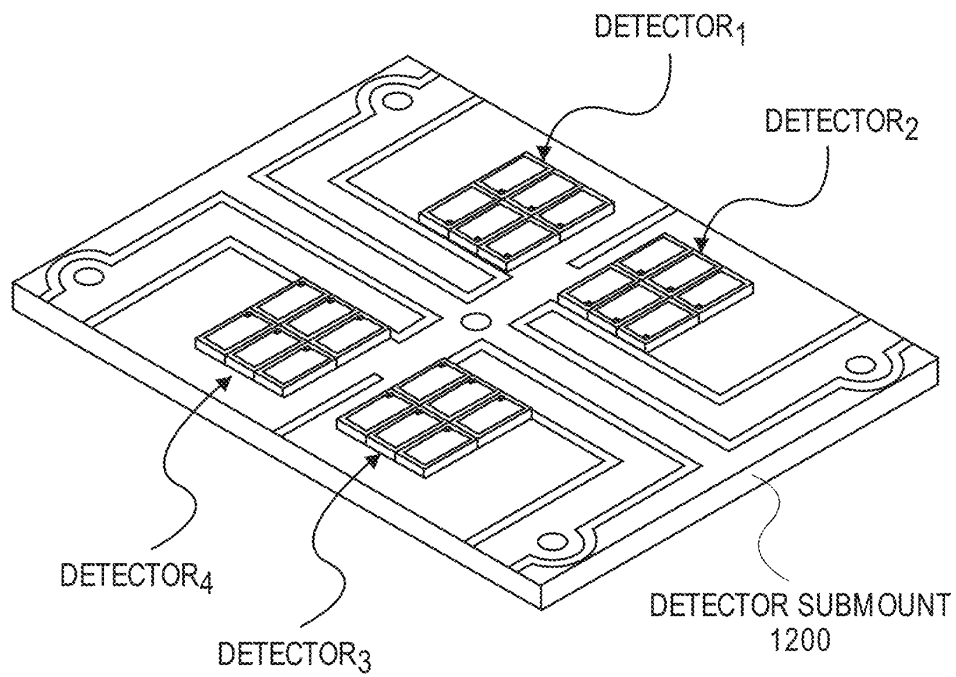


FIG. 12A

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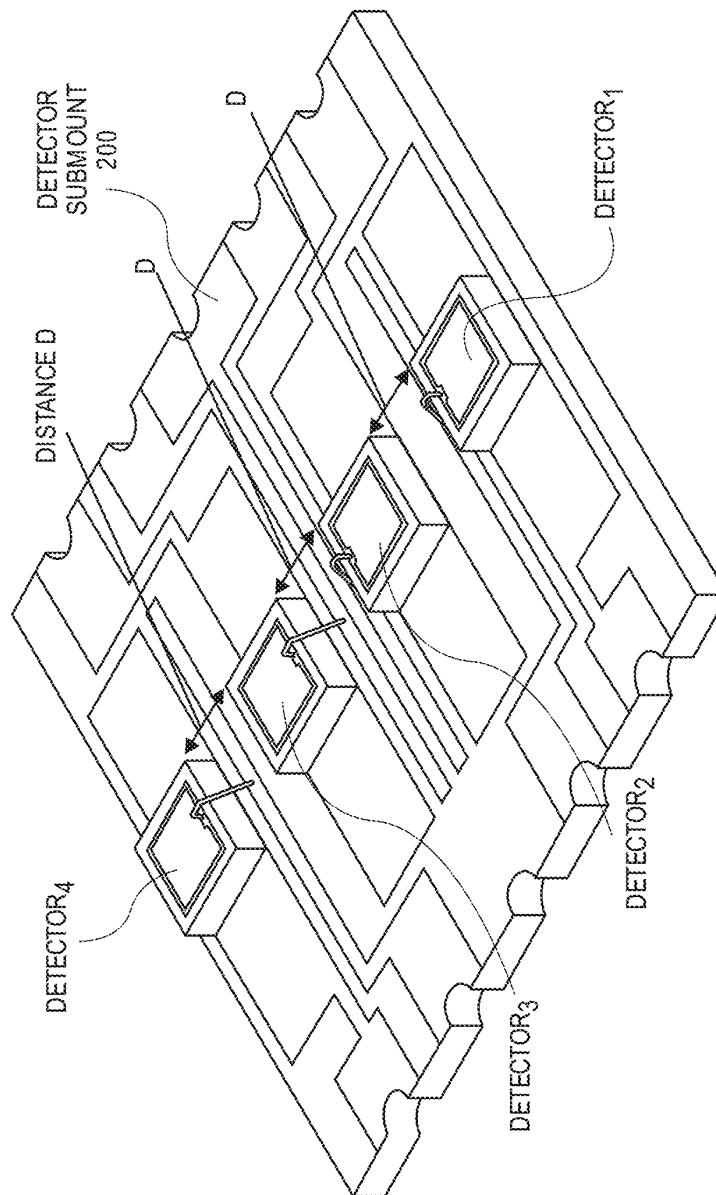


FIG. 12B

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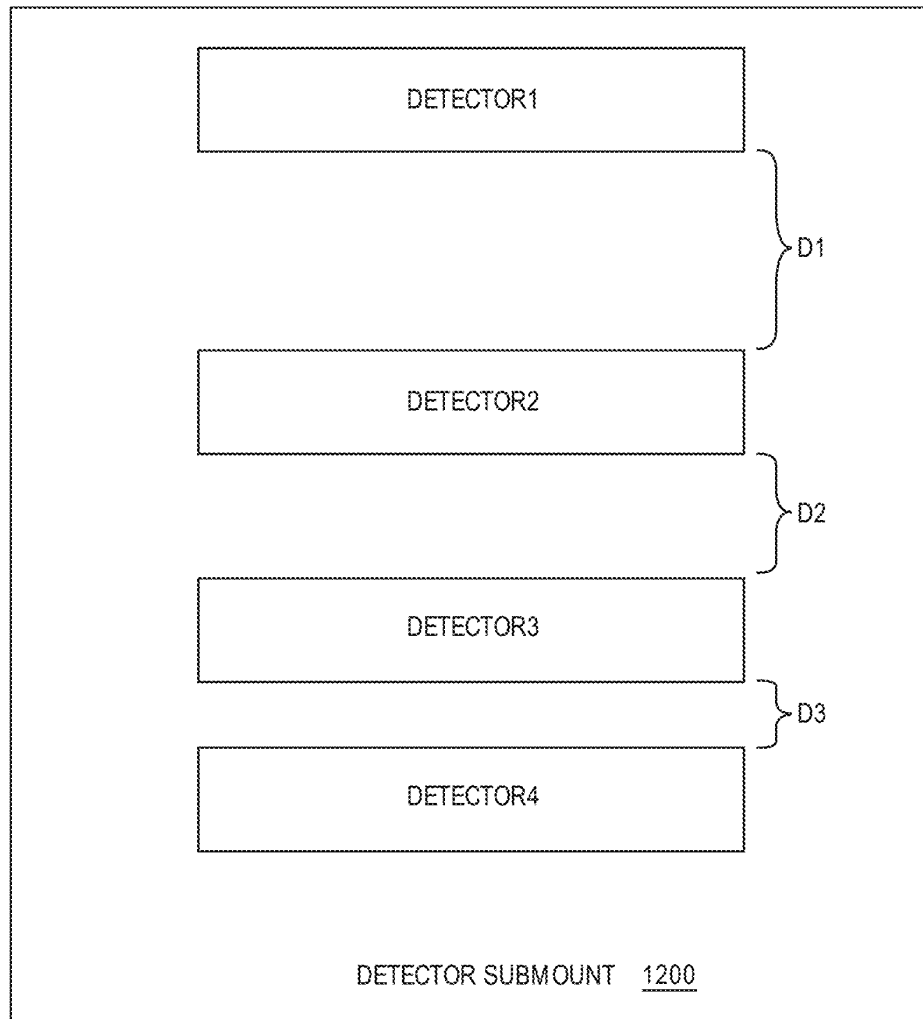


FIG. 12C

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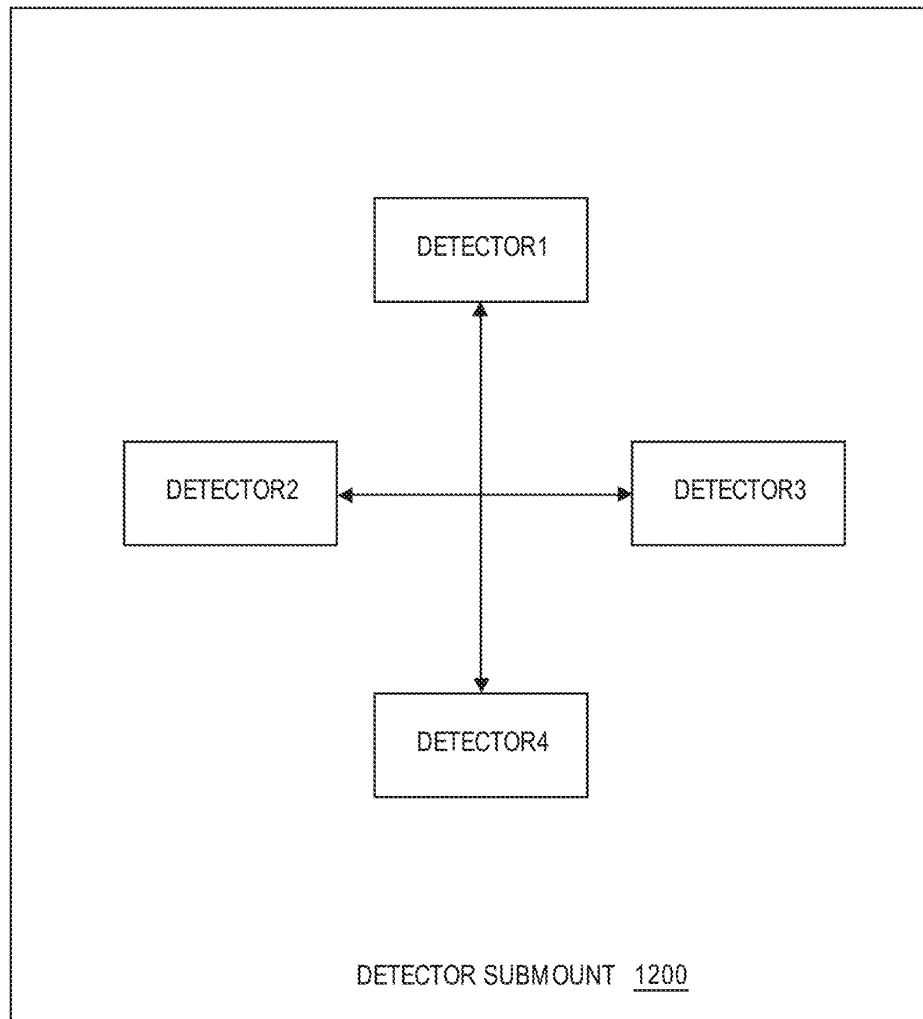


FIG. 12D

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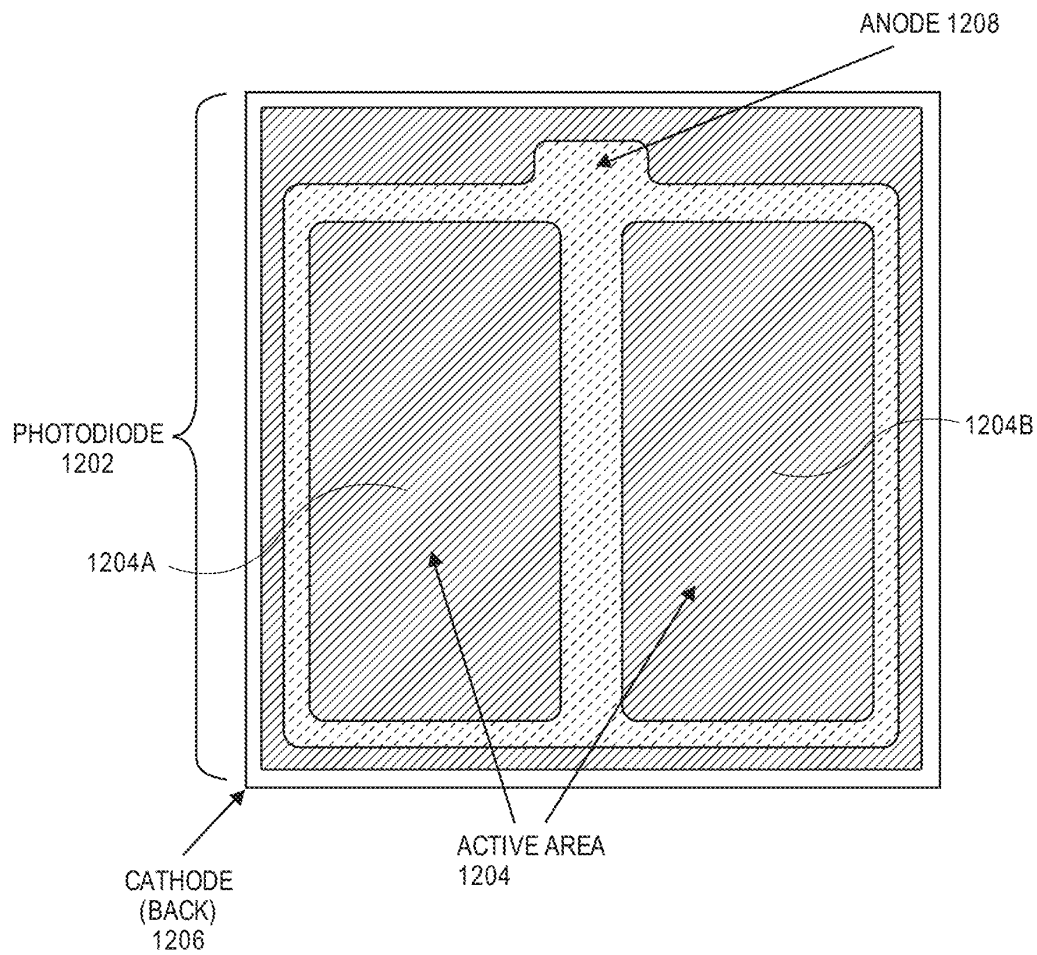


FIG. 12E

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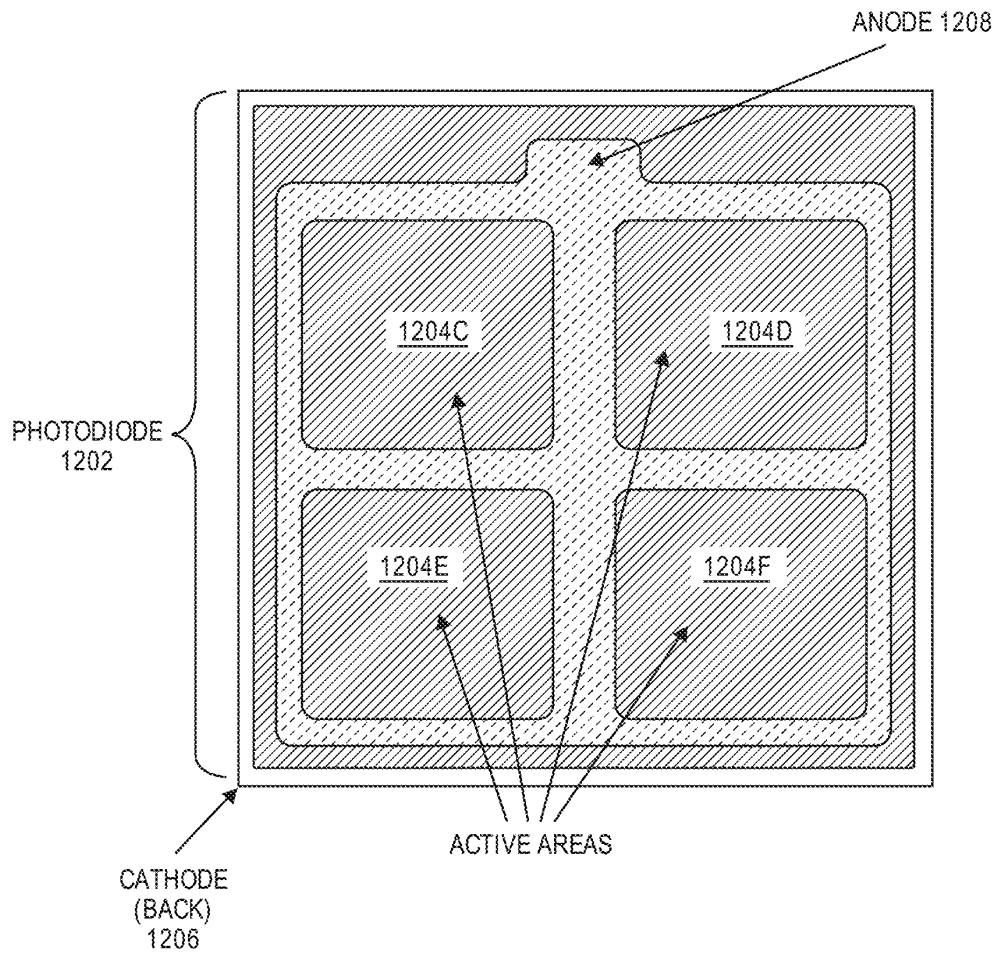


FIG. 12F

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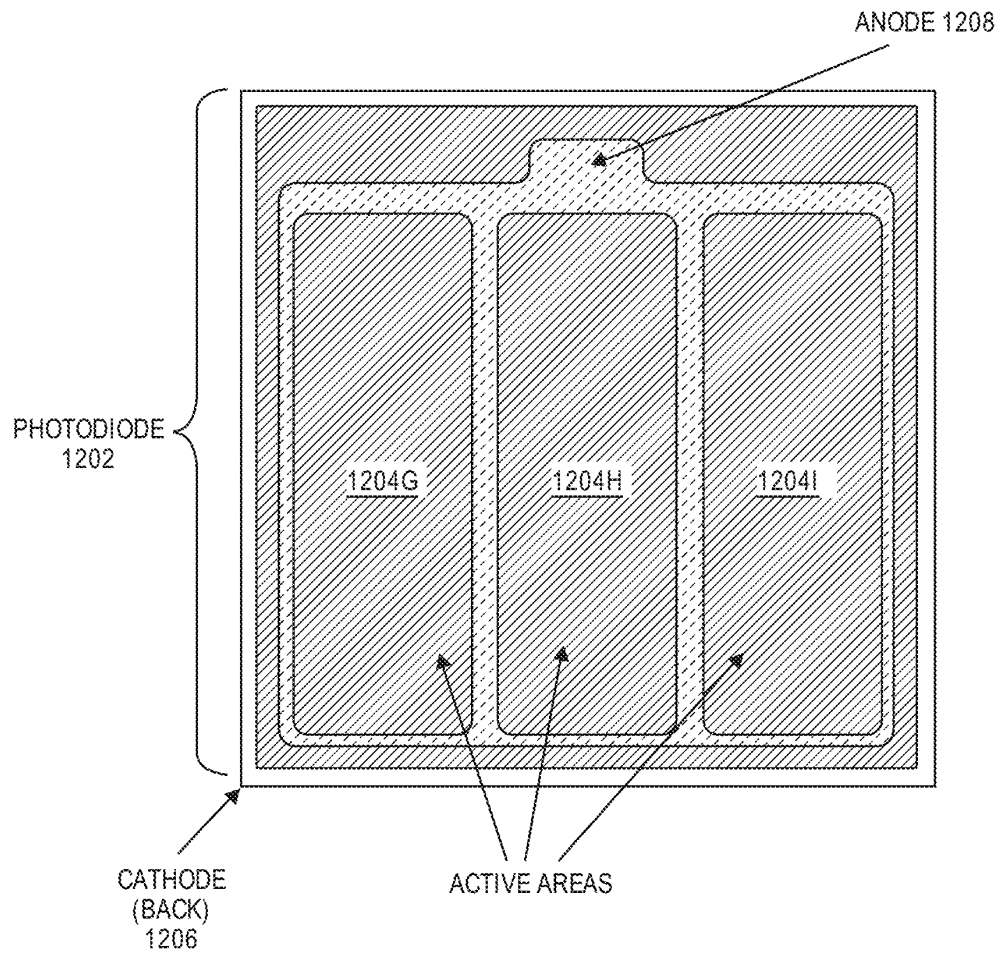


FIG. 12G

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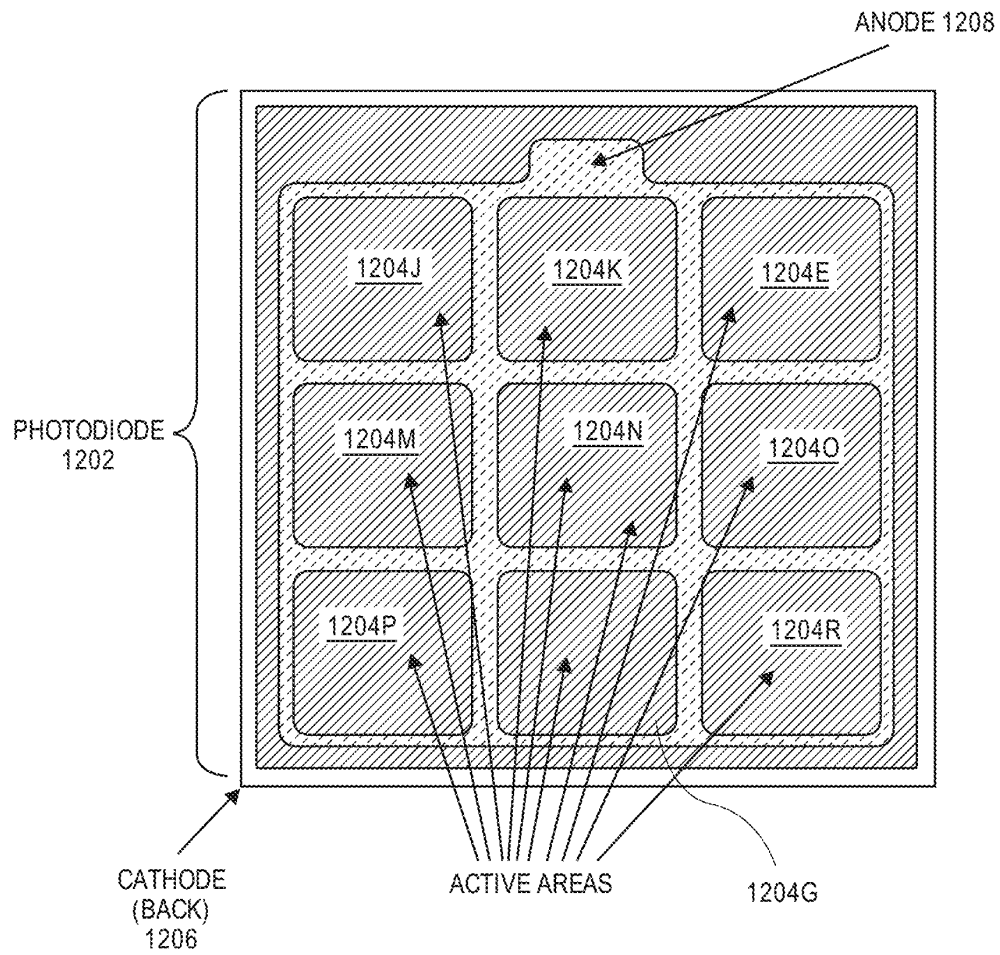


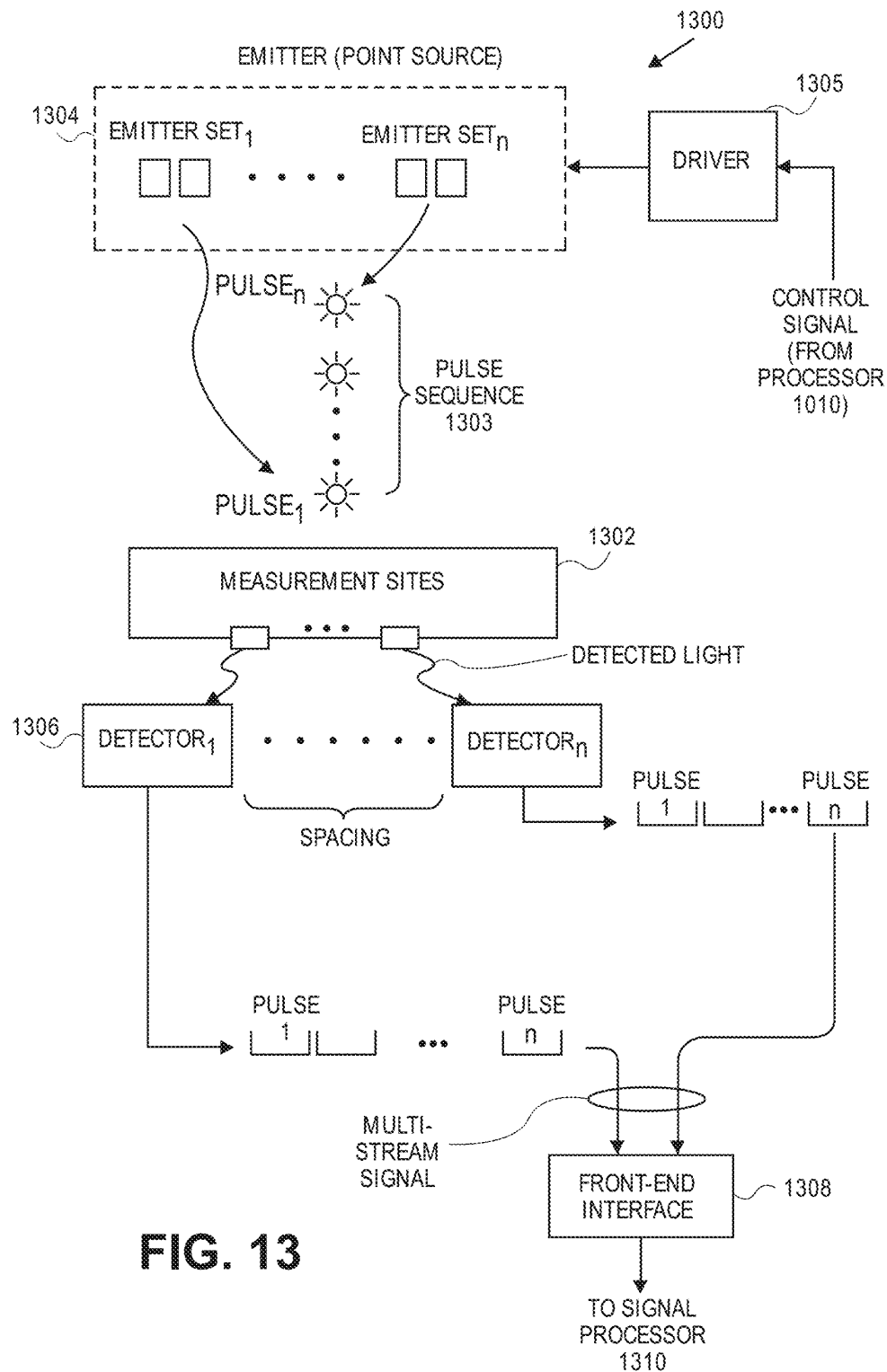
FIG. 12H

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**FIG. 13**

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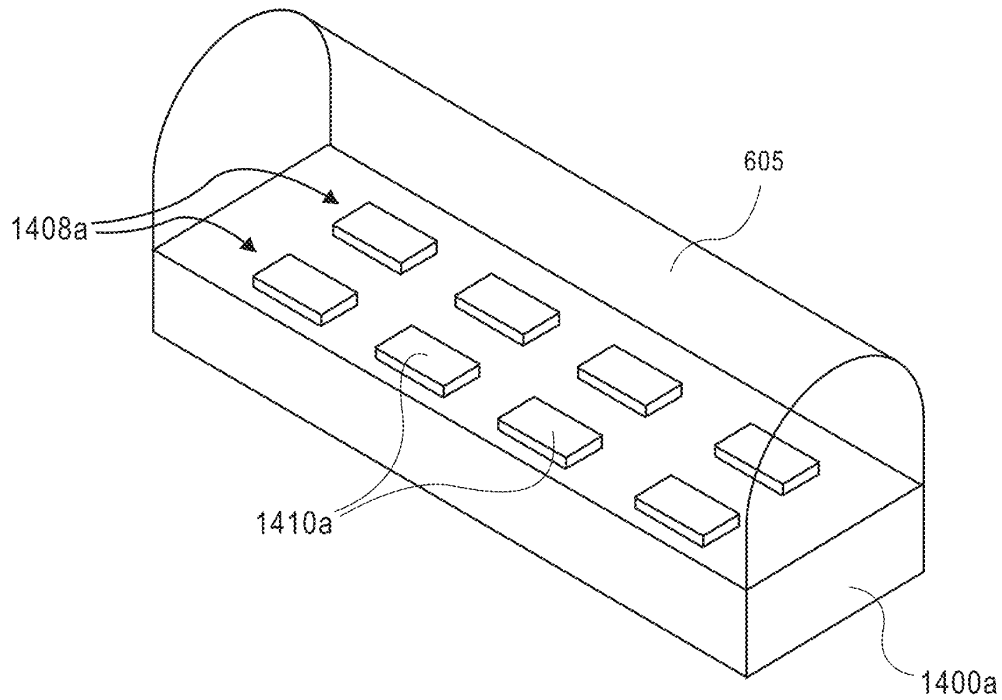


FIG. 14A

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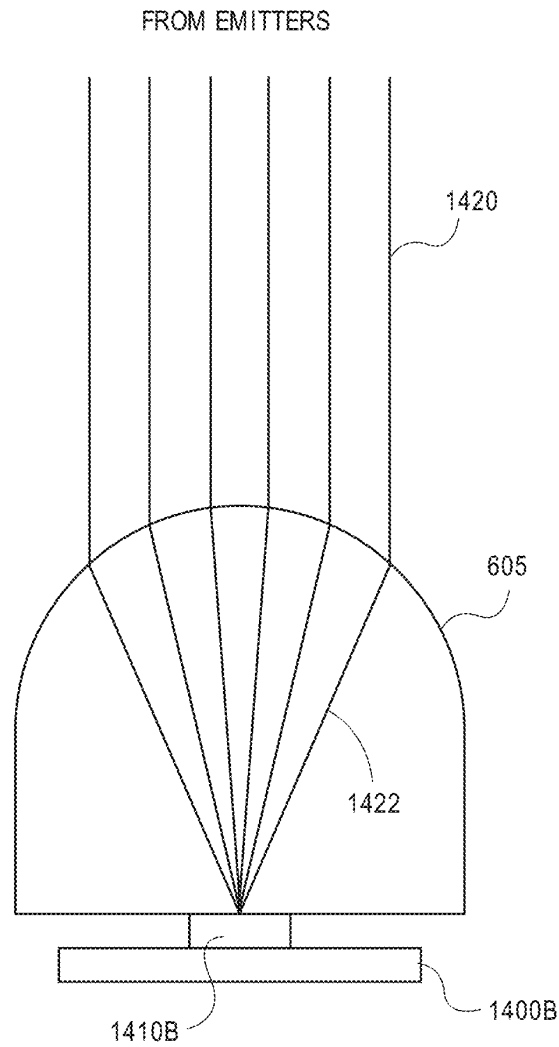


FIG. 14B

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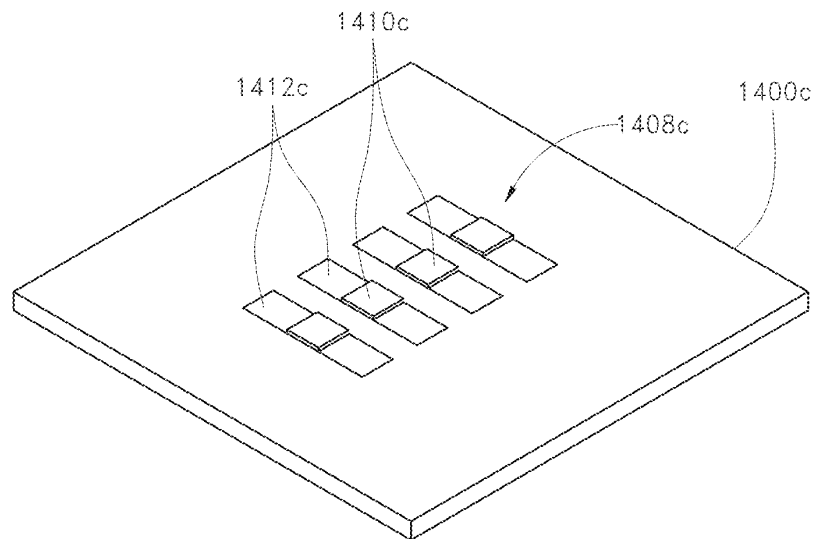


FIG. 14C

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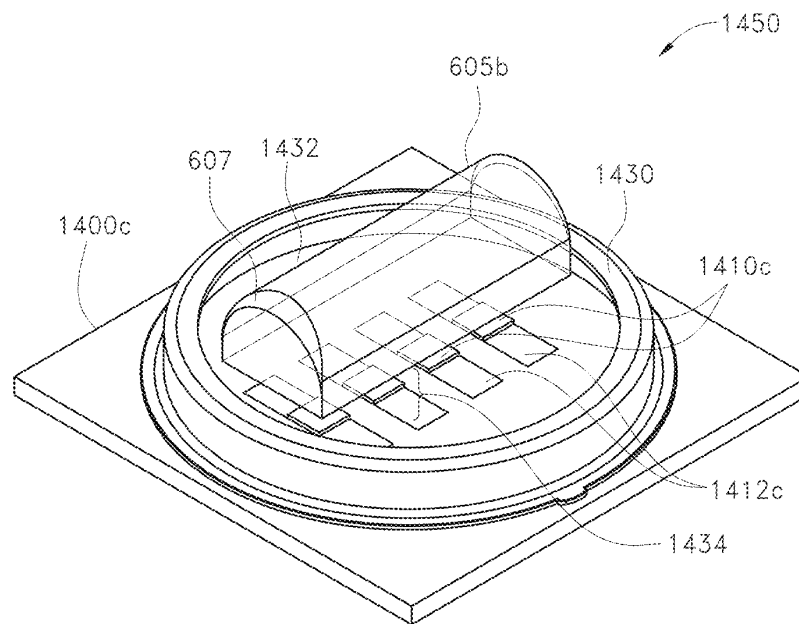


FIG. 14D

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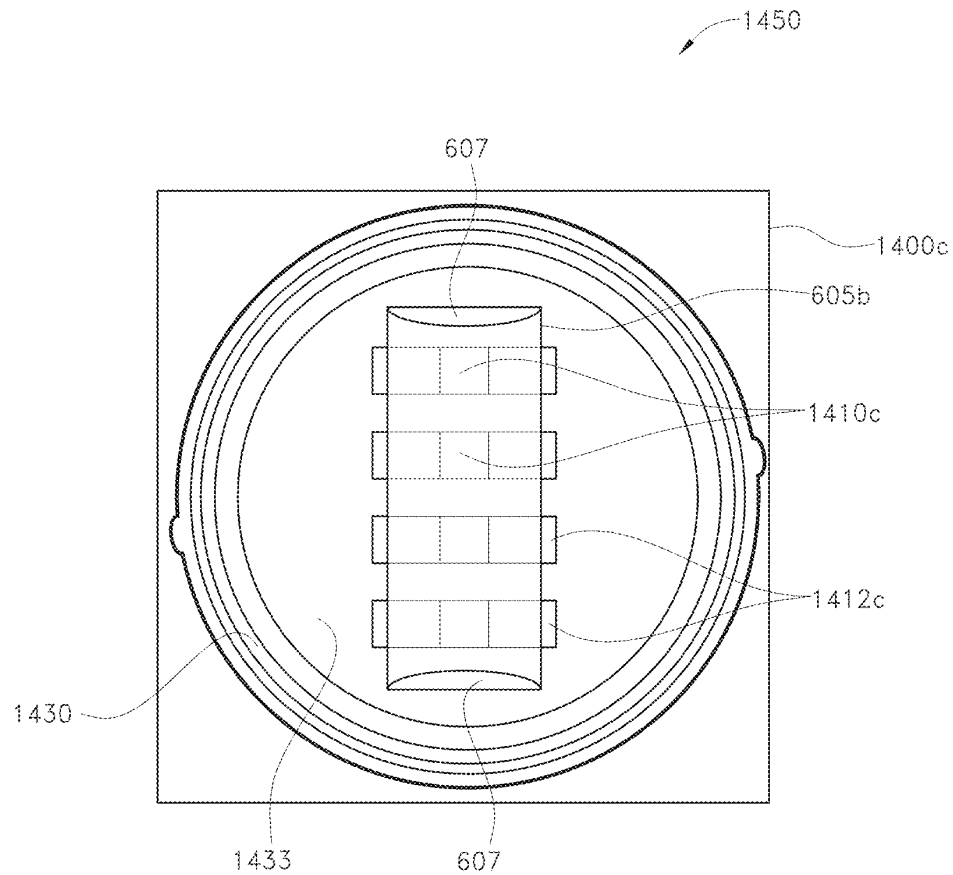


FIG. 14E

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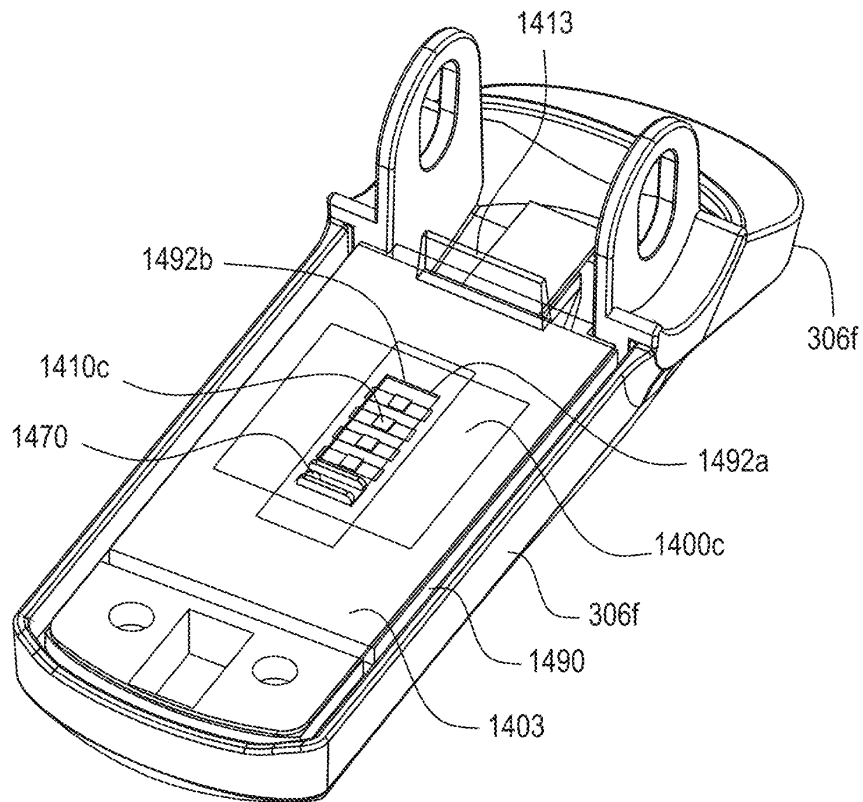


FIG. 14F

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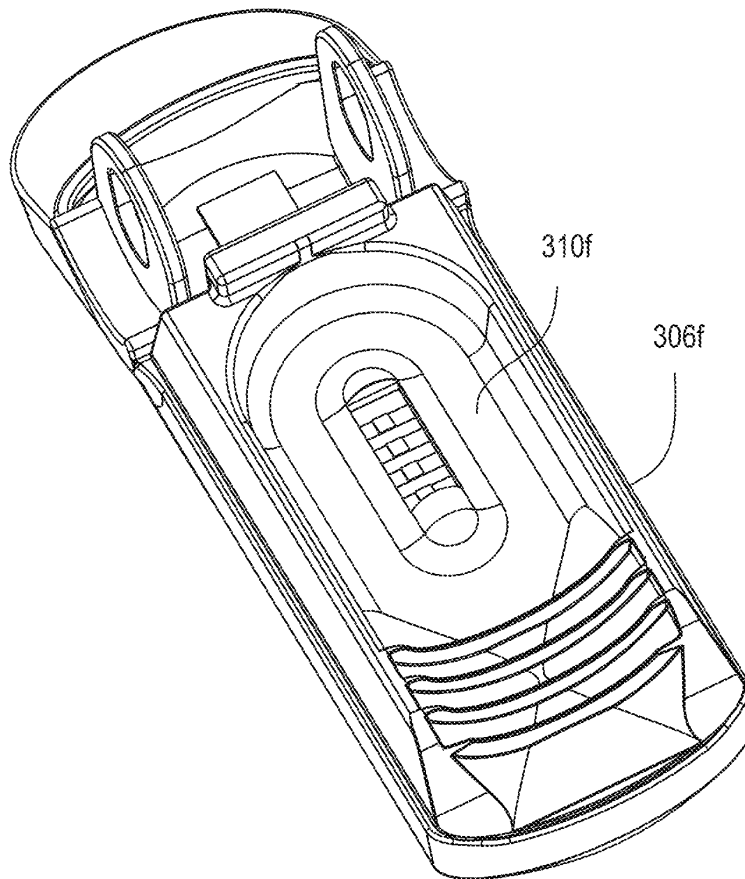


FIG. 14G

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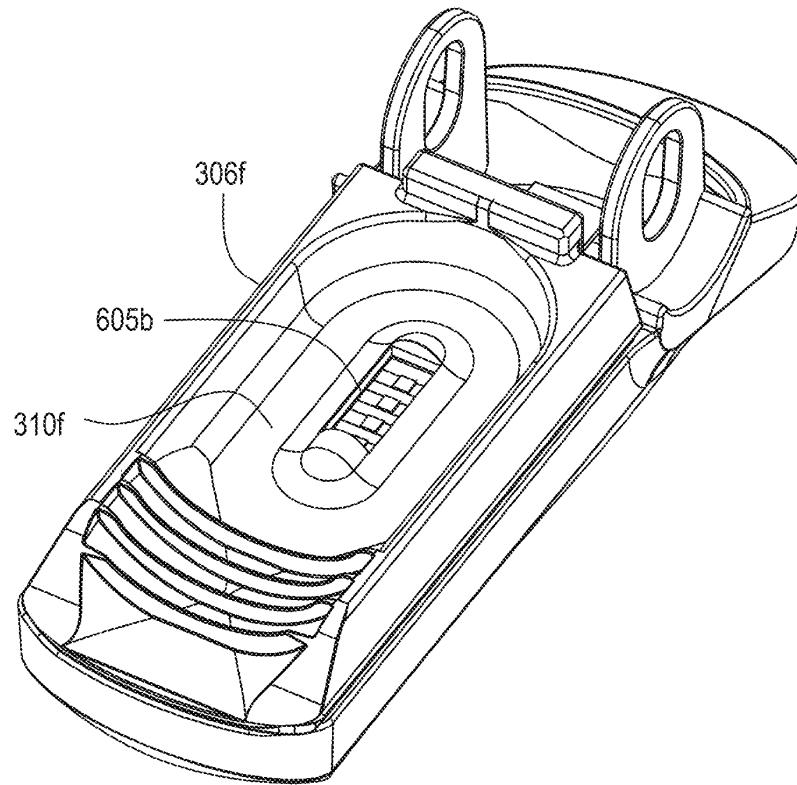


FIG. 14H

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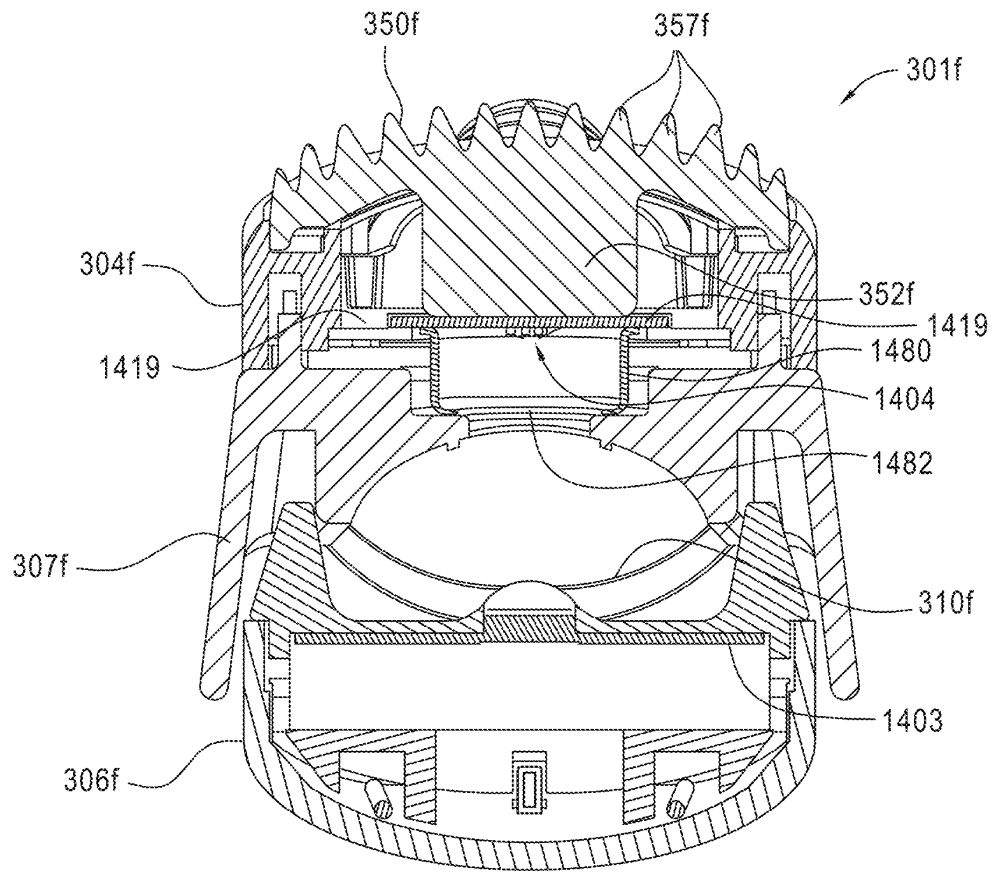


FIG. 14I

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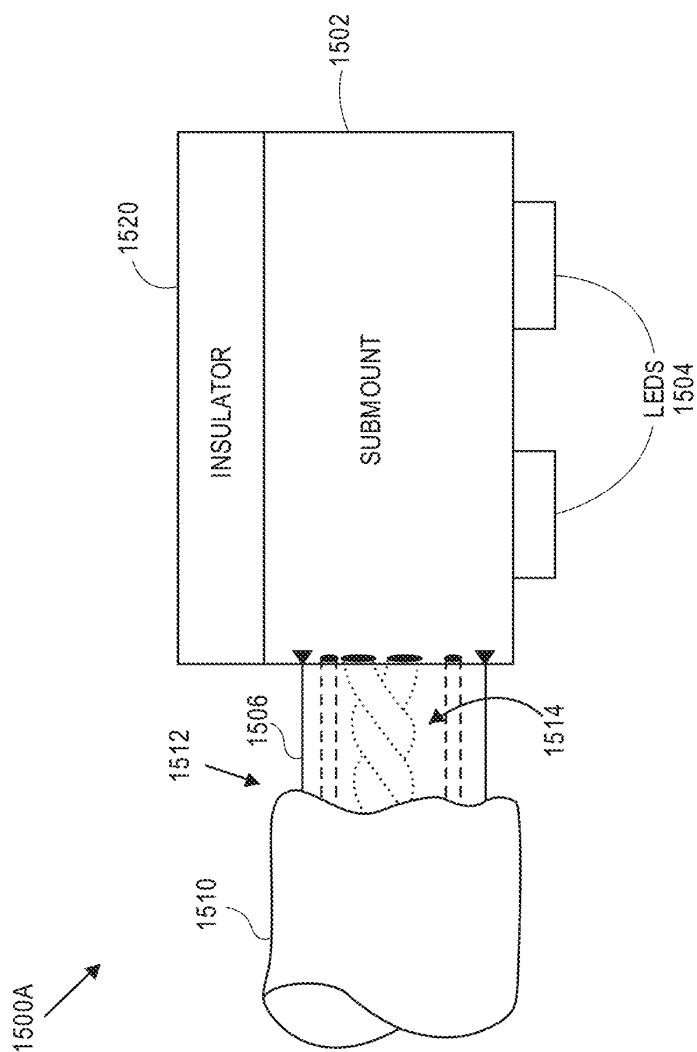


FIG. 15A

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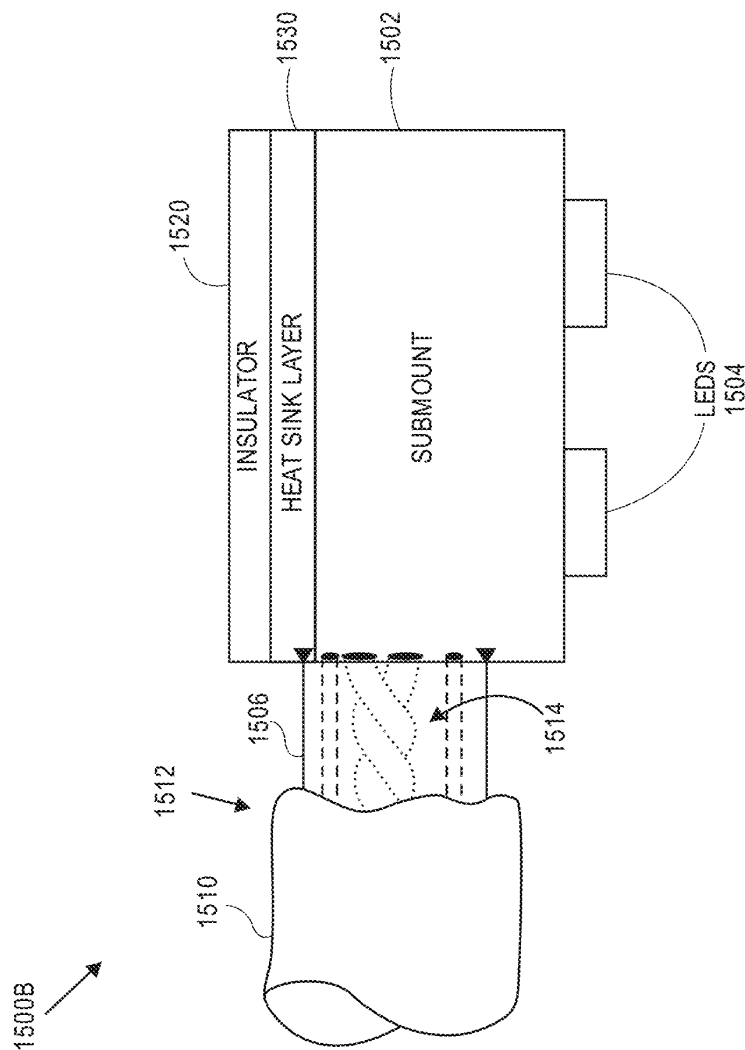


FIG. 15B

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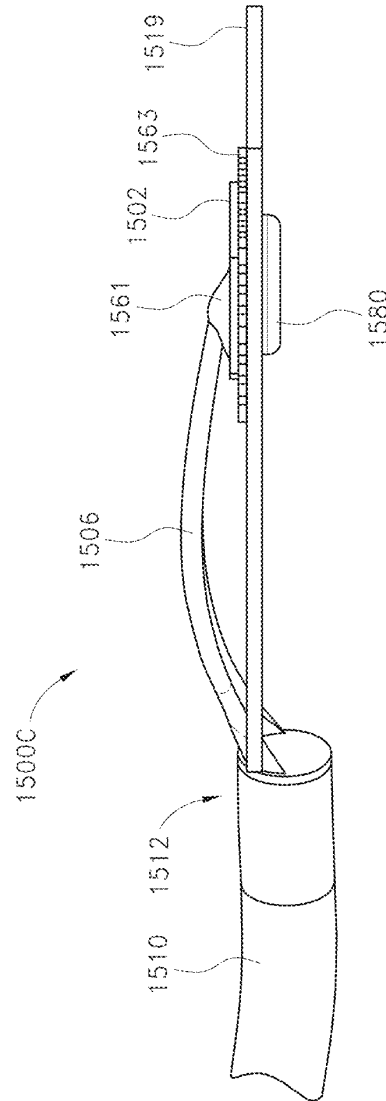


FIG. 15C

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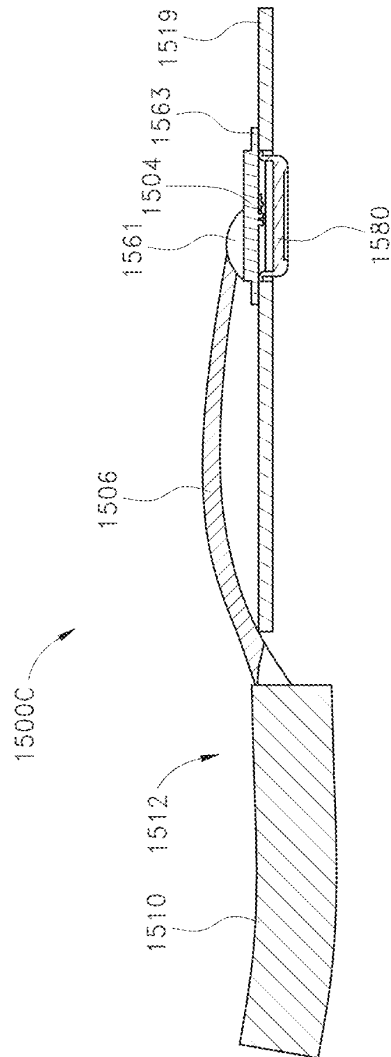


FIG. 15D

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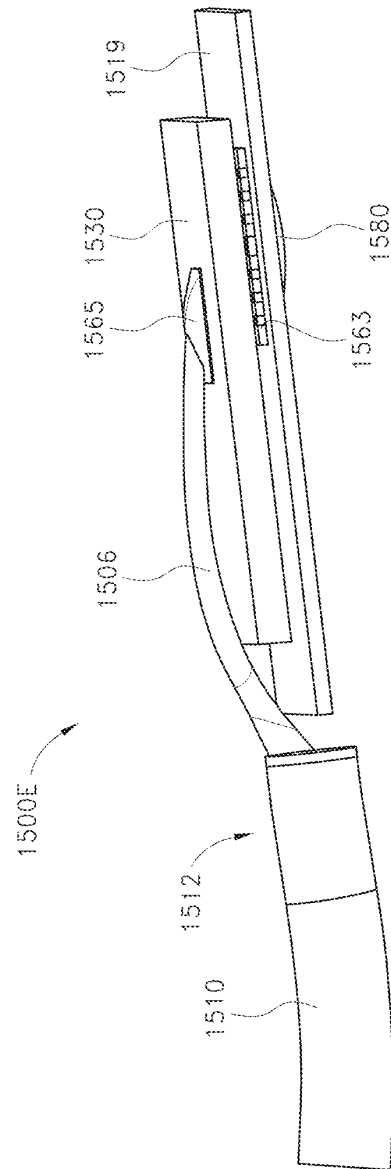


FIG. 15E

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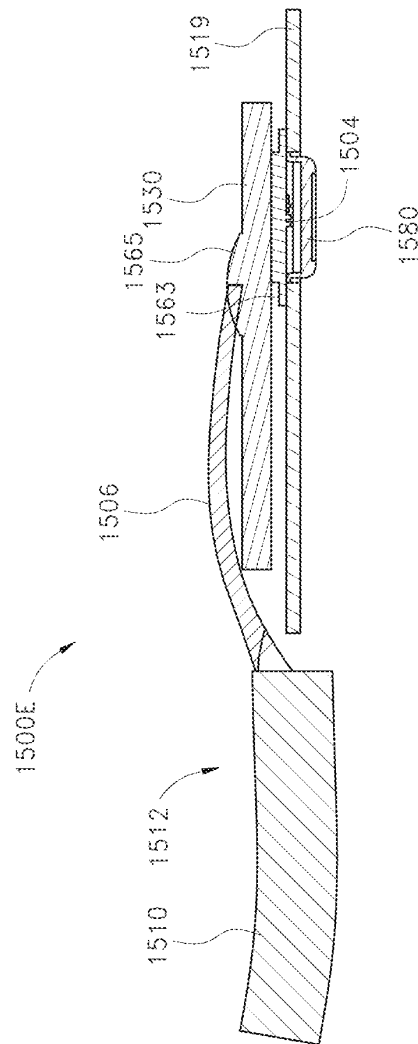


FIG. 15F

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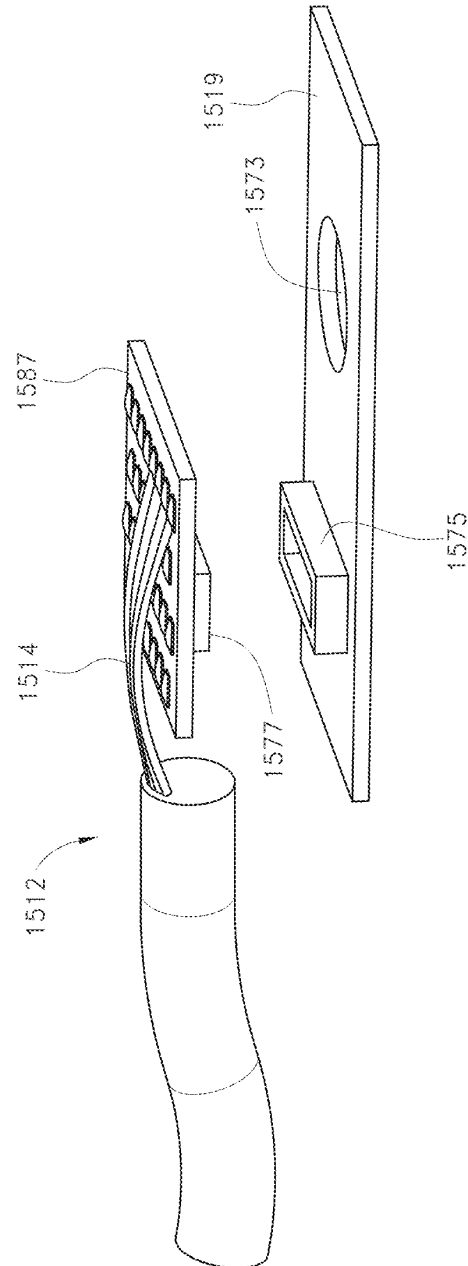


FIG. 15G

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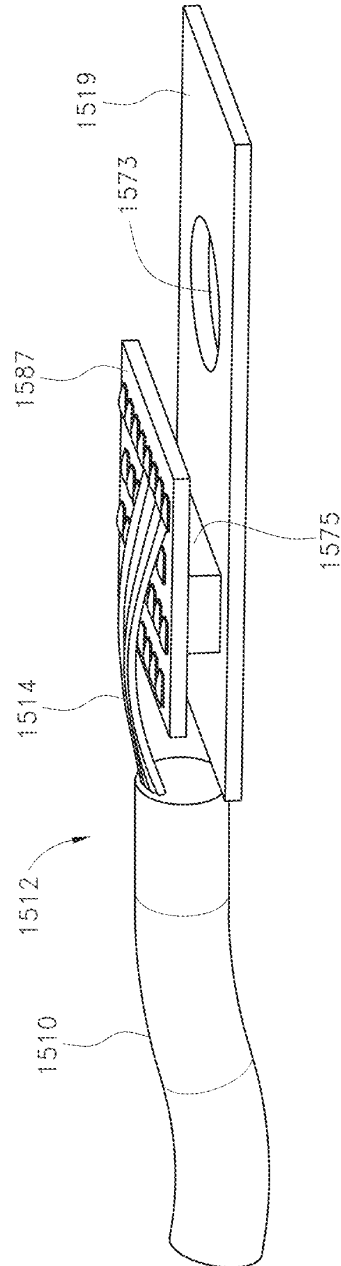


FIG. 15H

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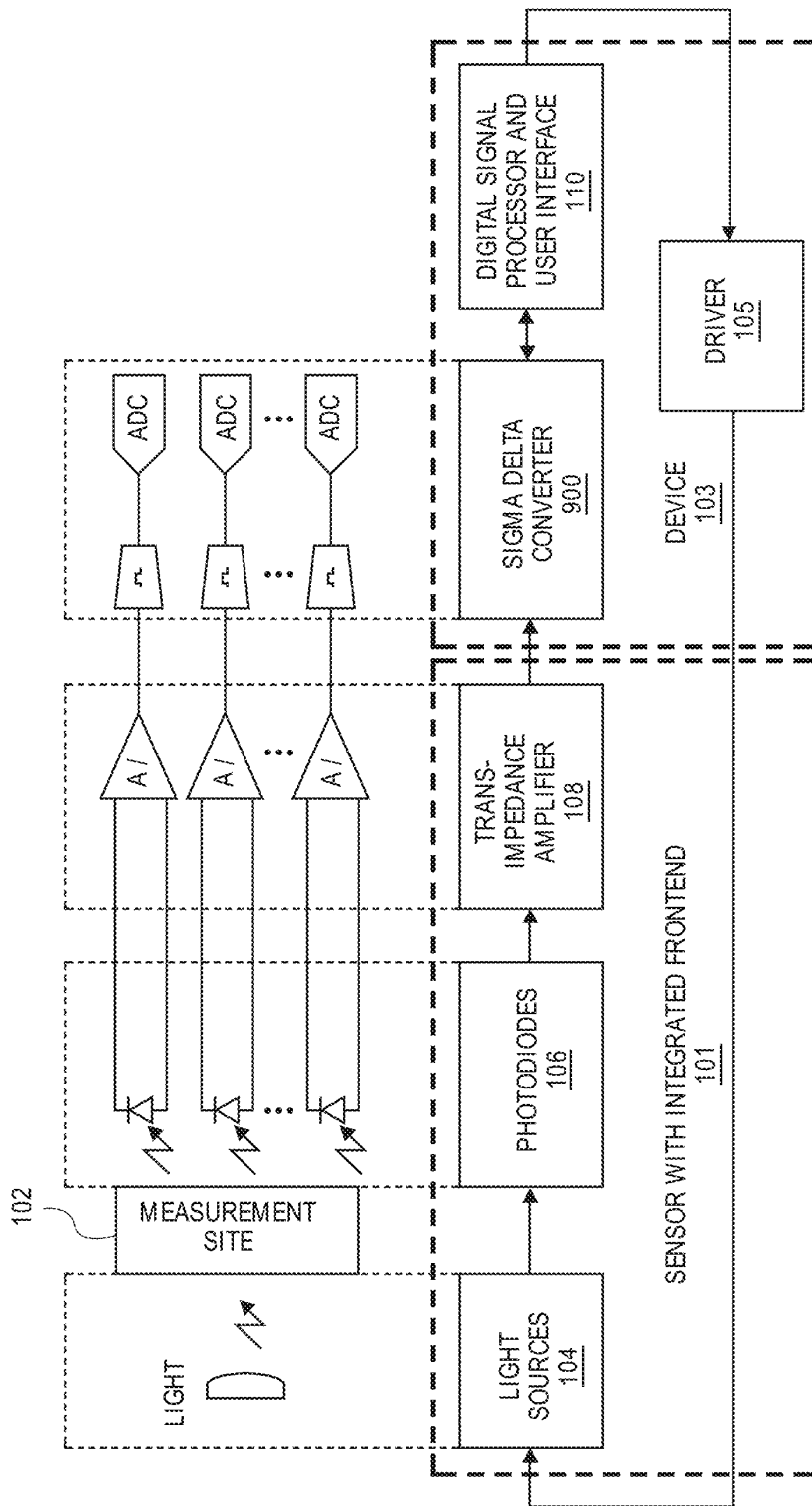


FIG. 15I

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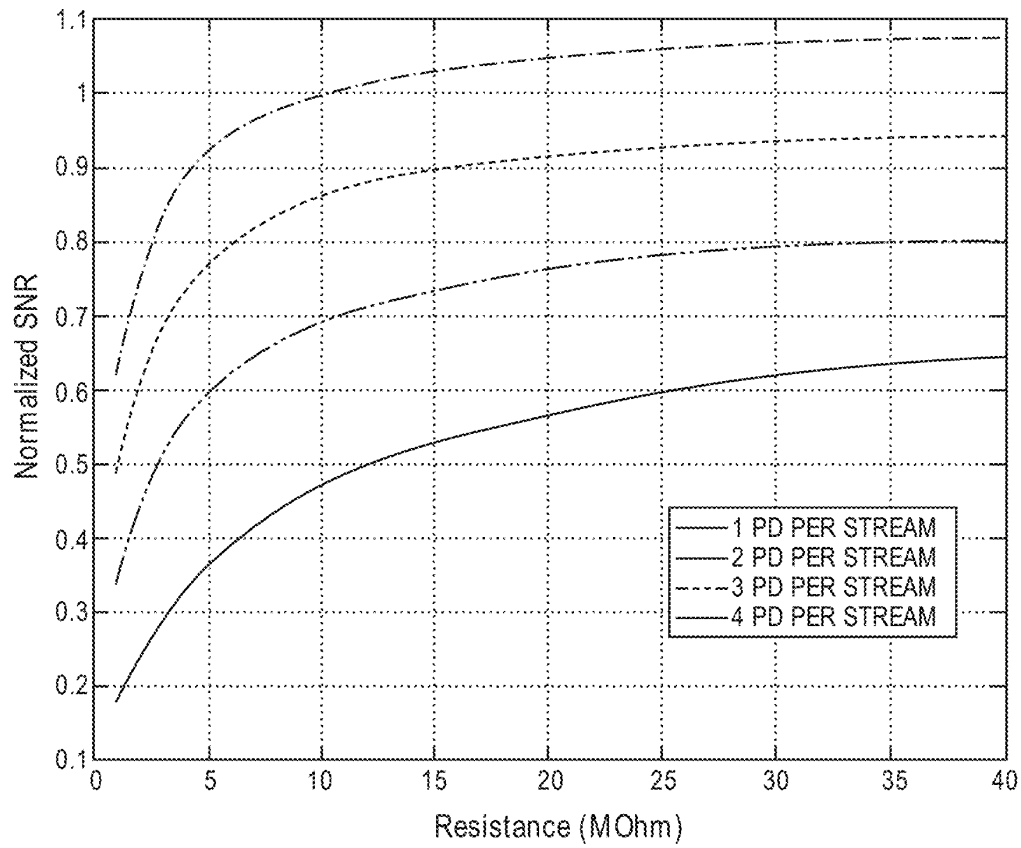
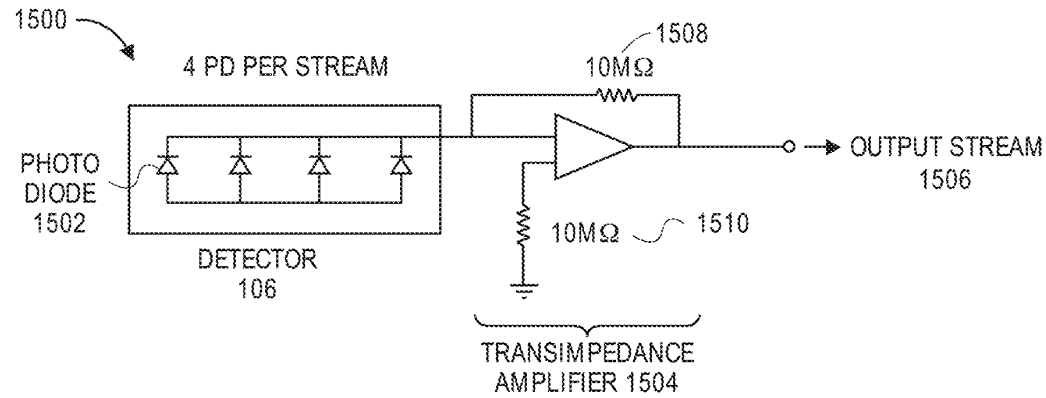


FIG. 15J

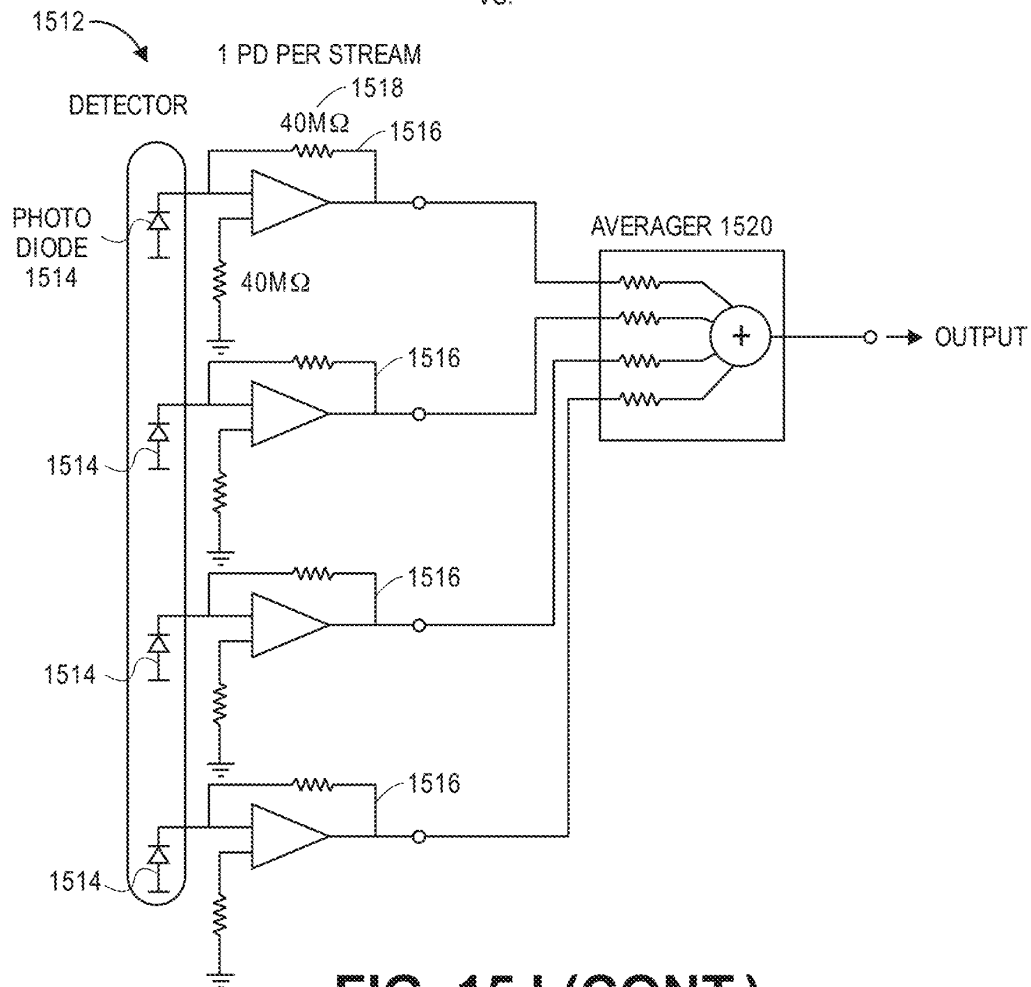
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VS.

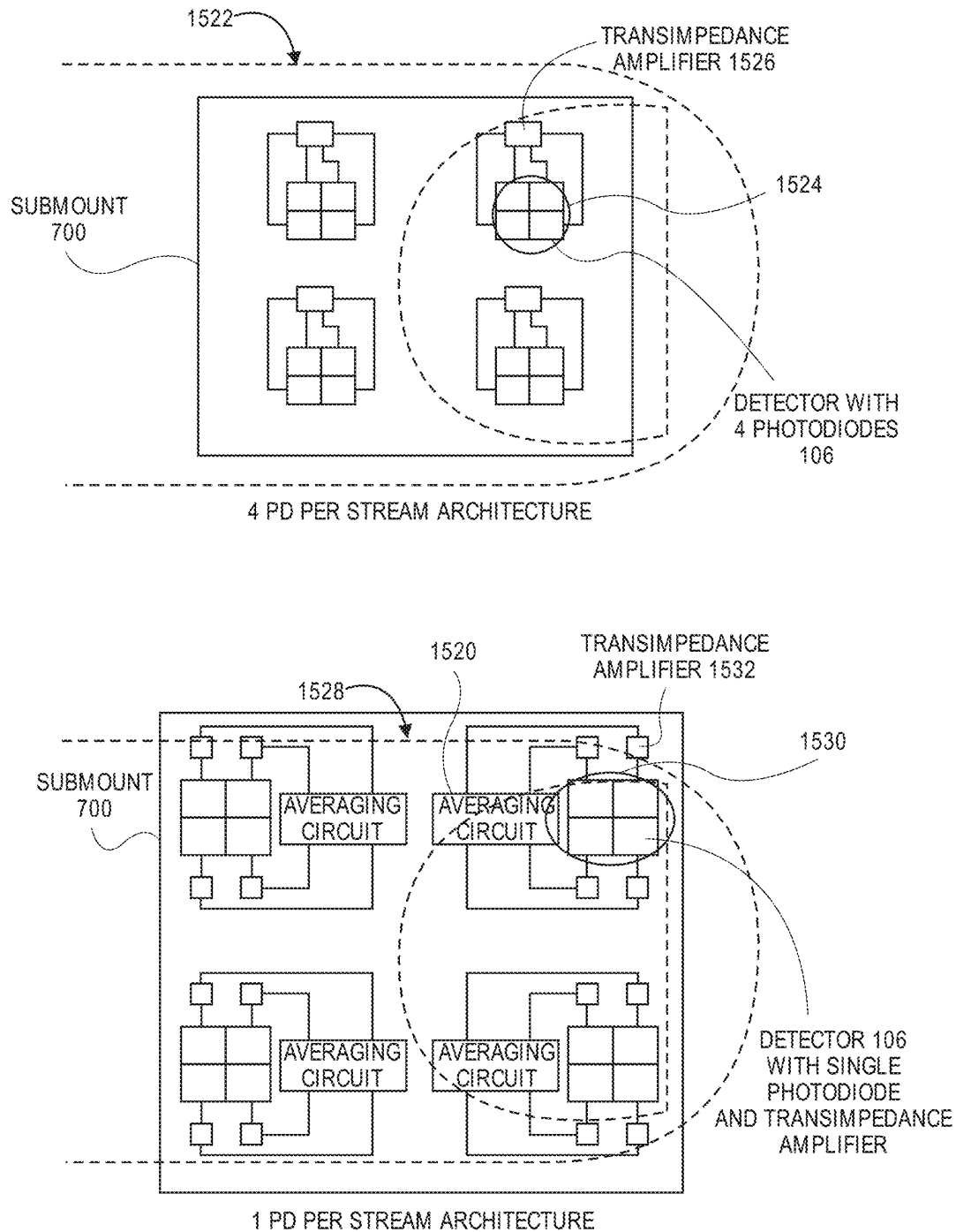
**FIG. 15J (CONT.)**

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**FIG. 15K**

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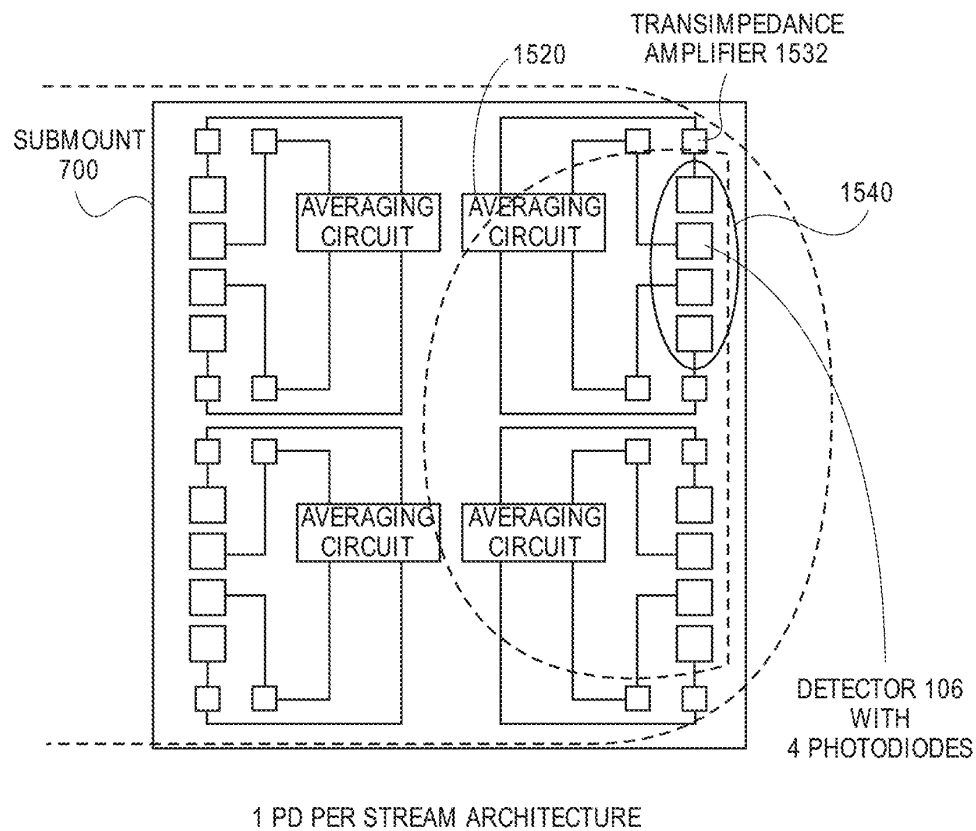
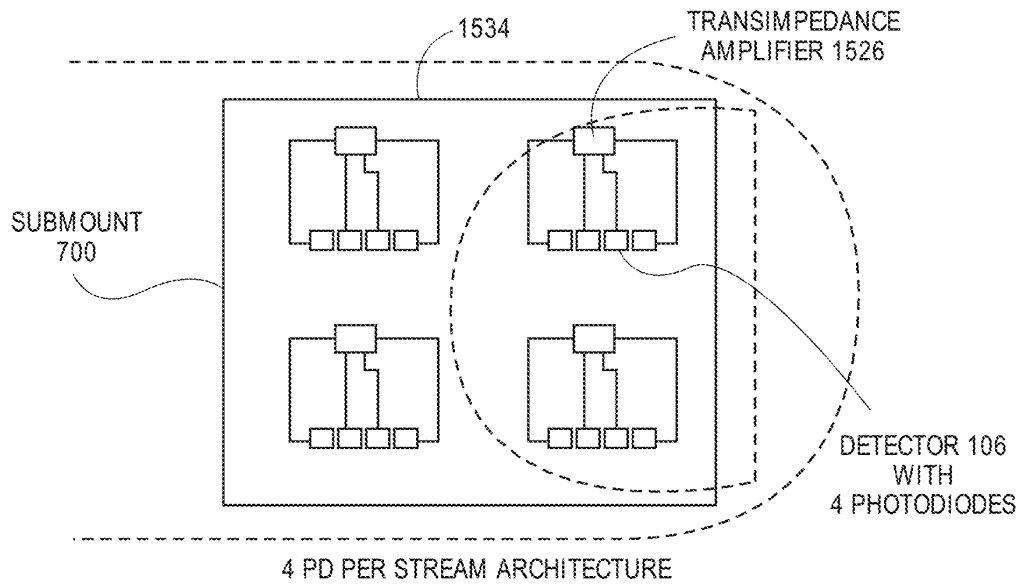


FIG. 15K (CONT.)

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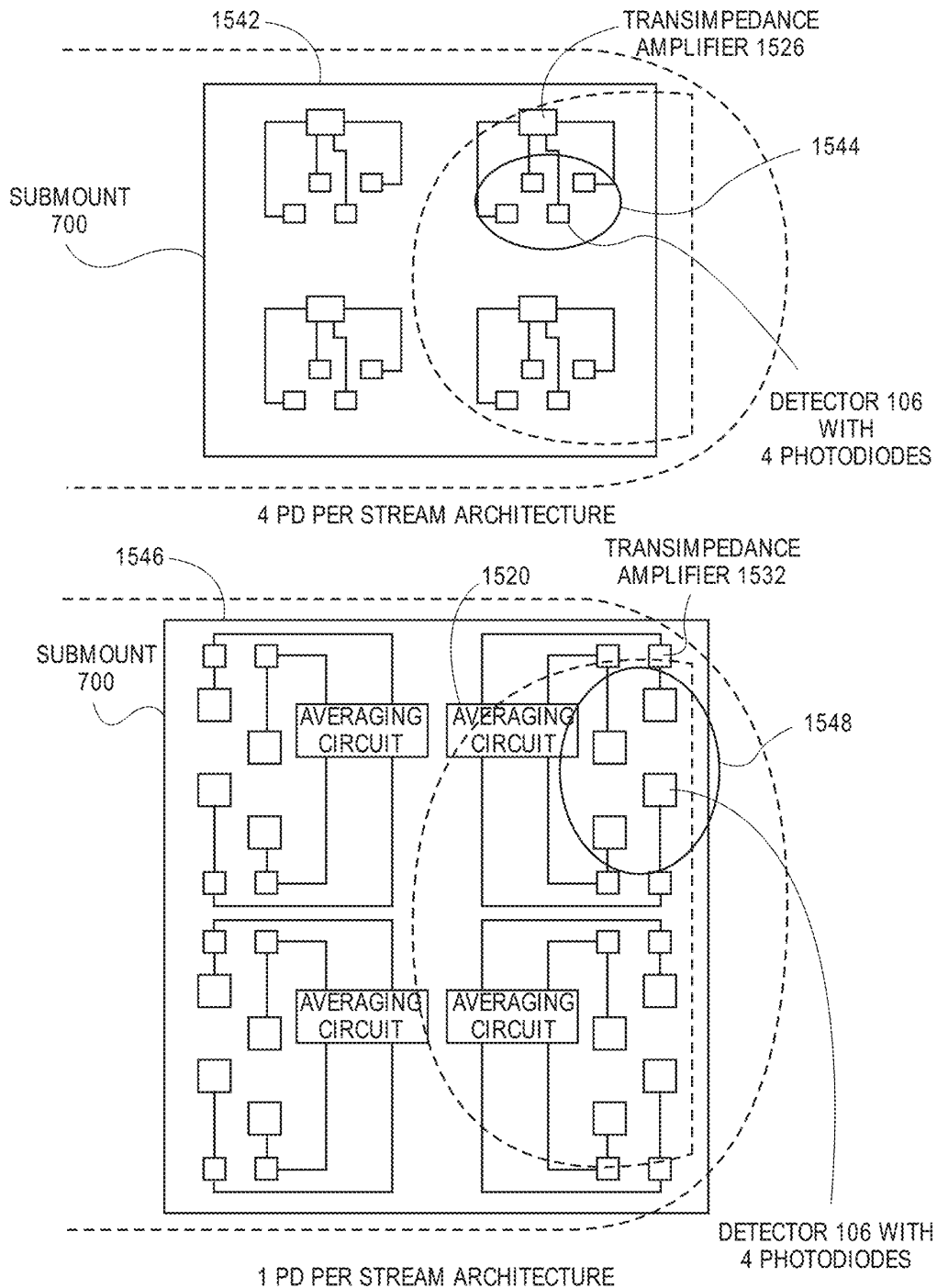


FIG. 15K (CONT.)

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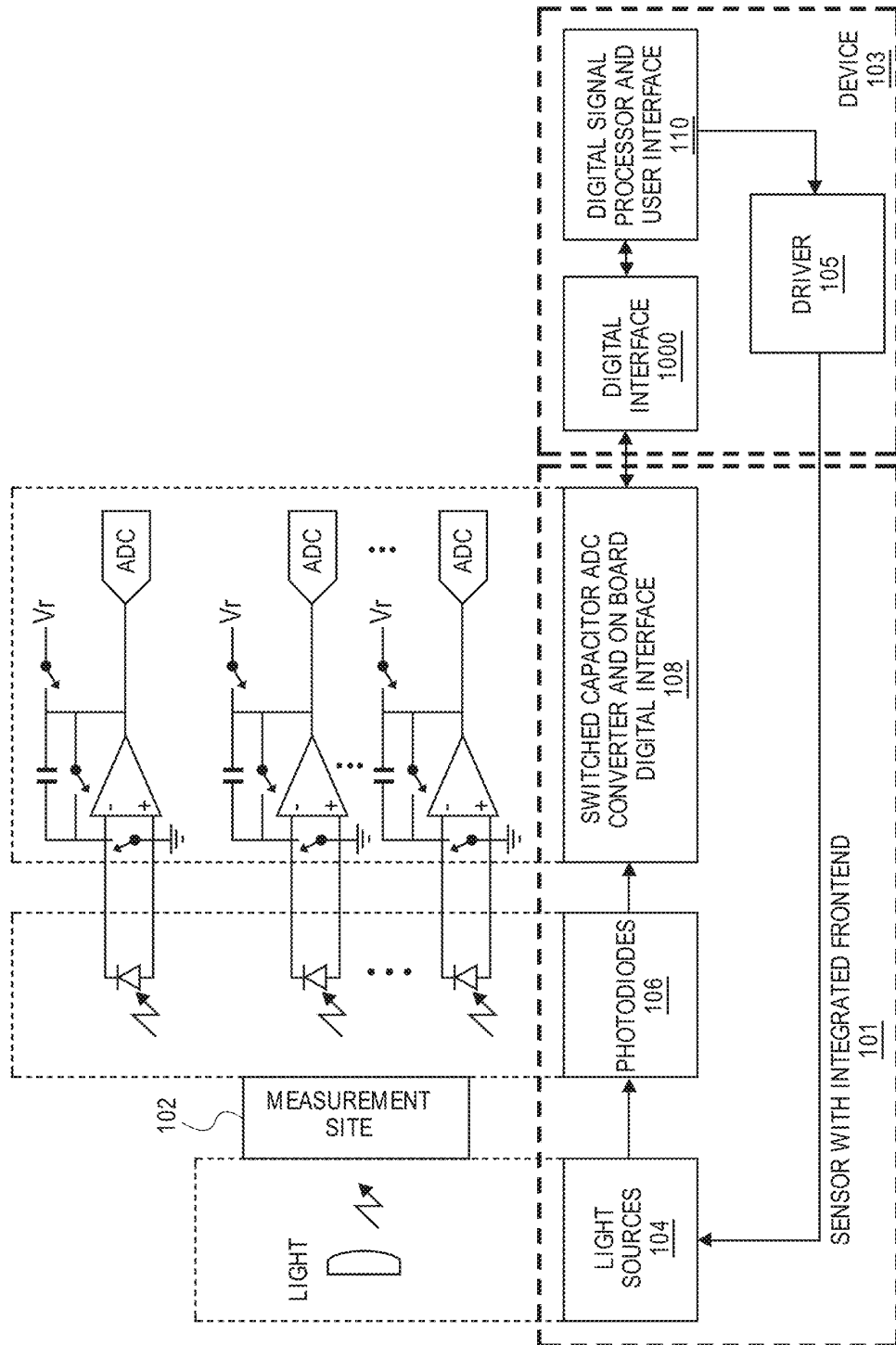


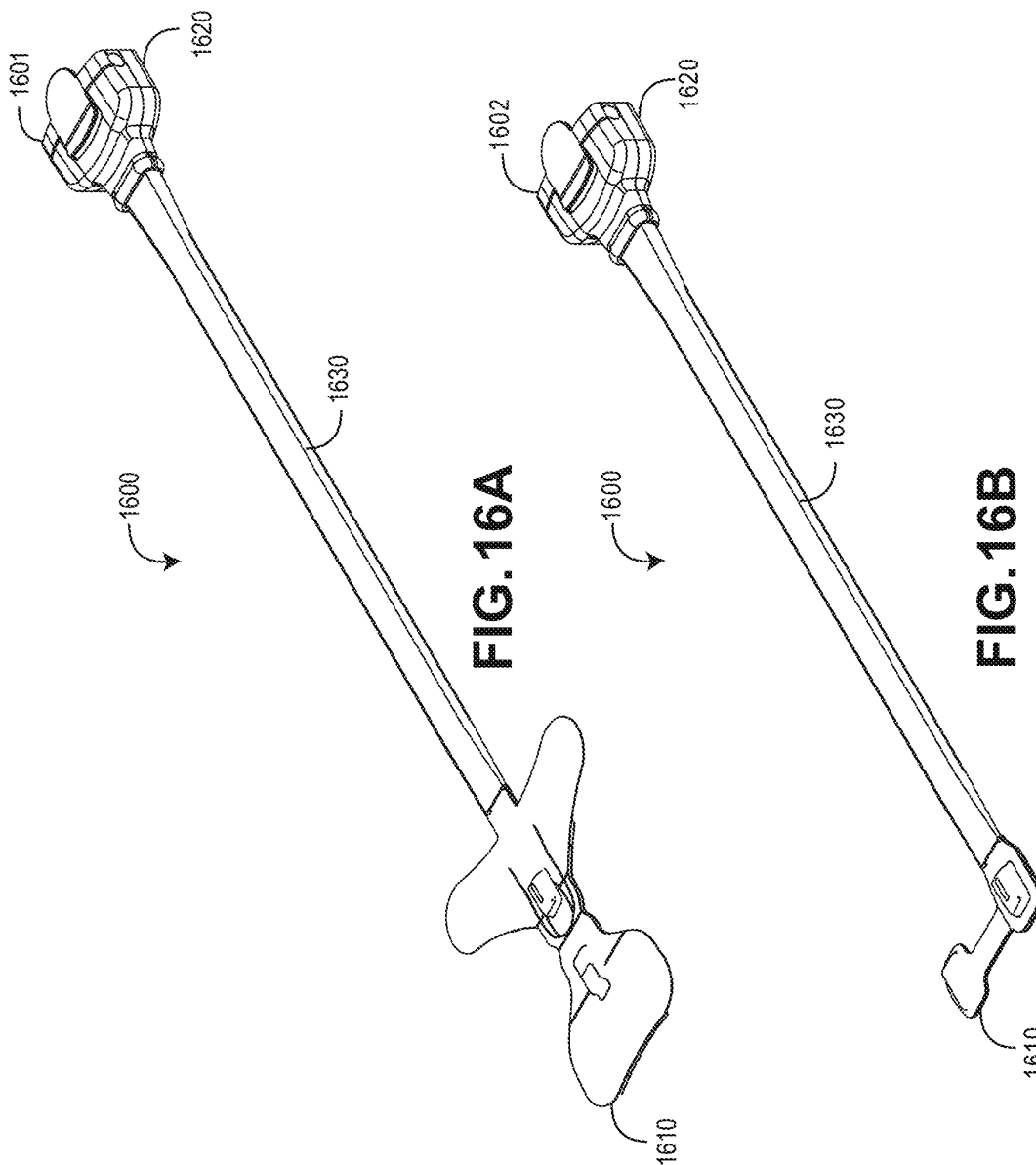
FIG. 15L

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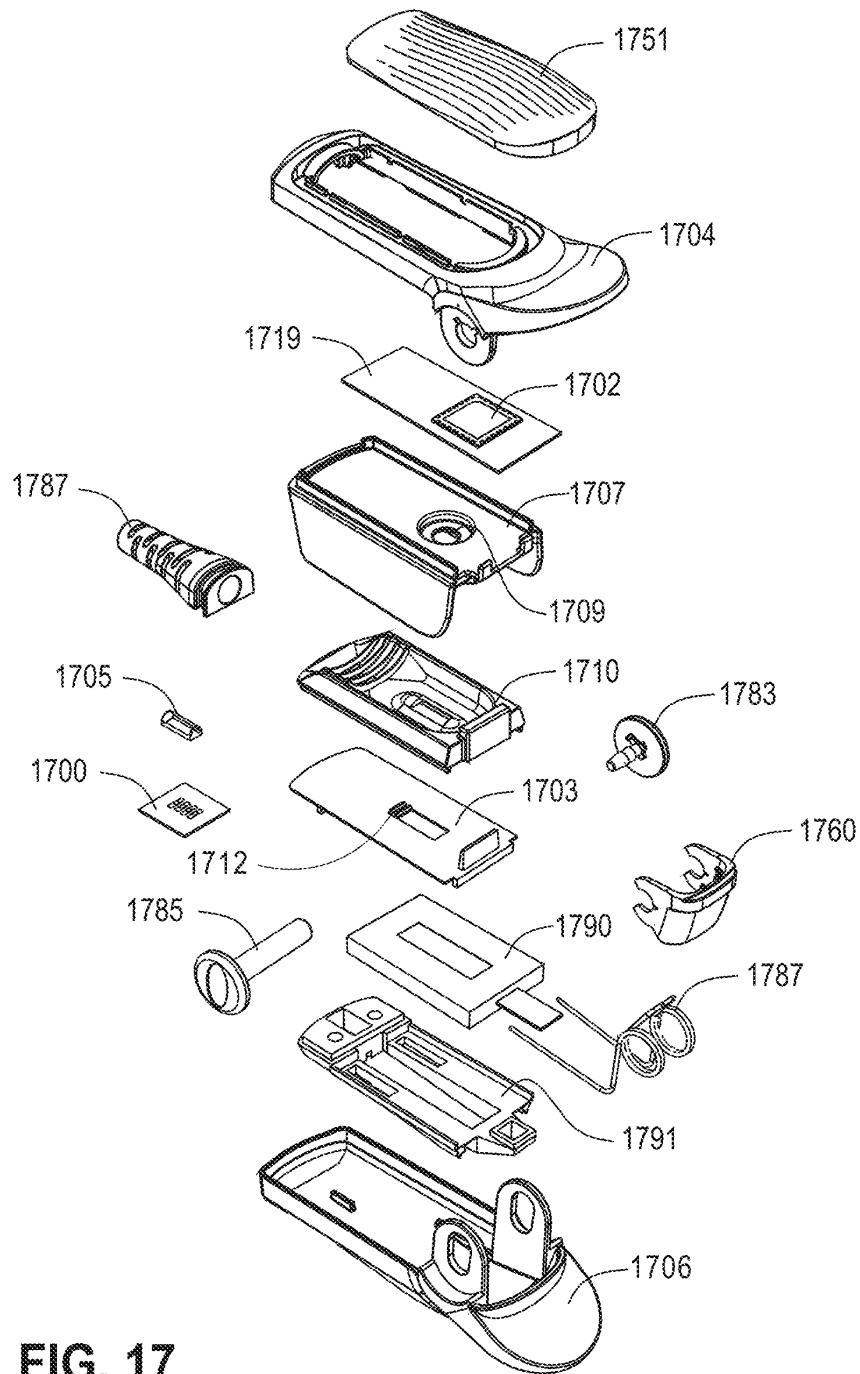
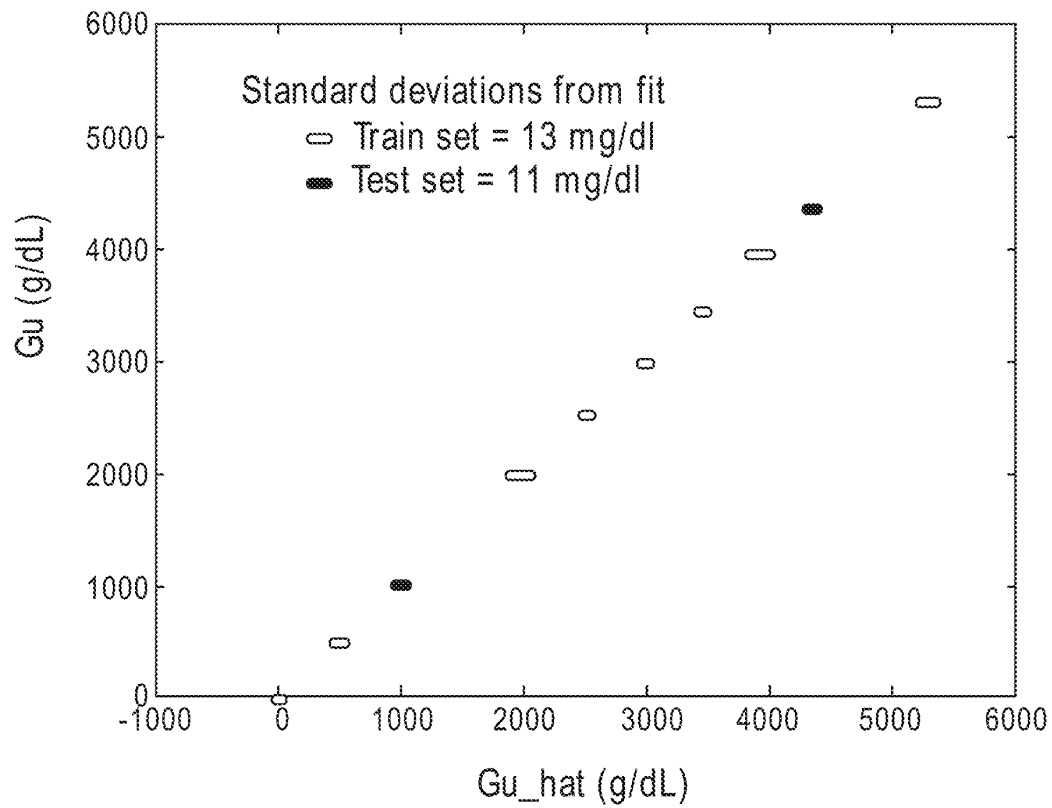


FIG. 17

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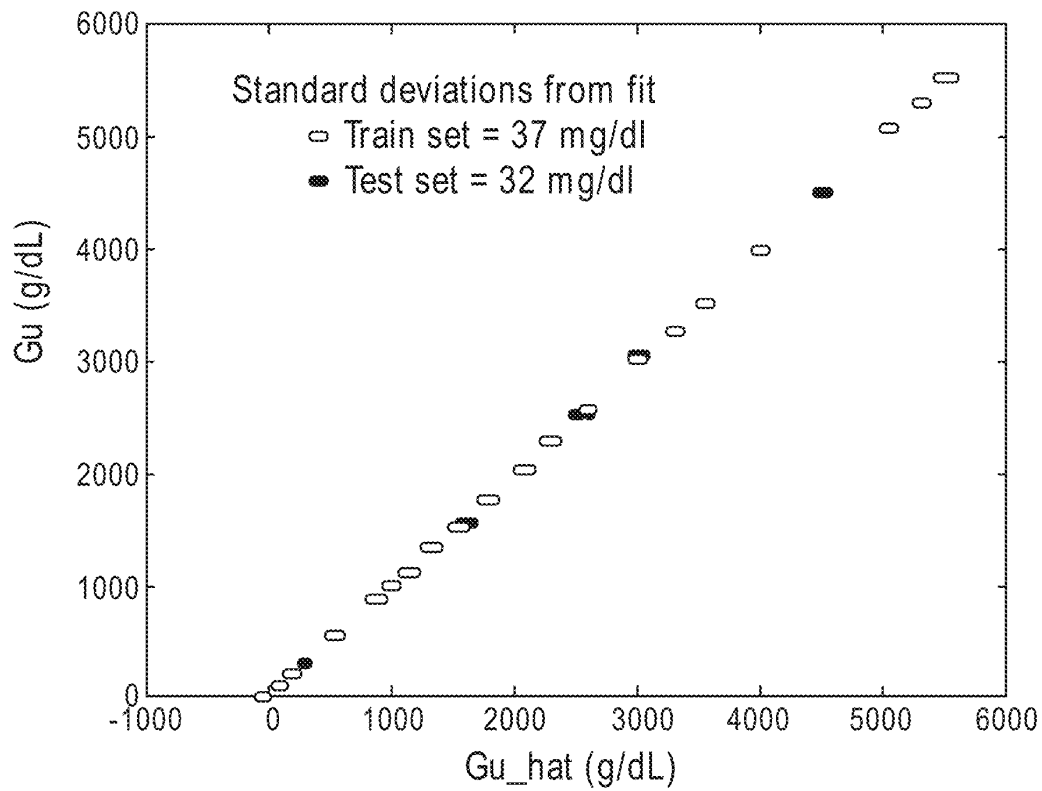


FIG. 19

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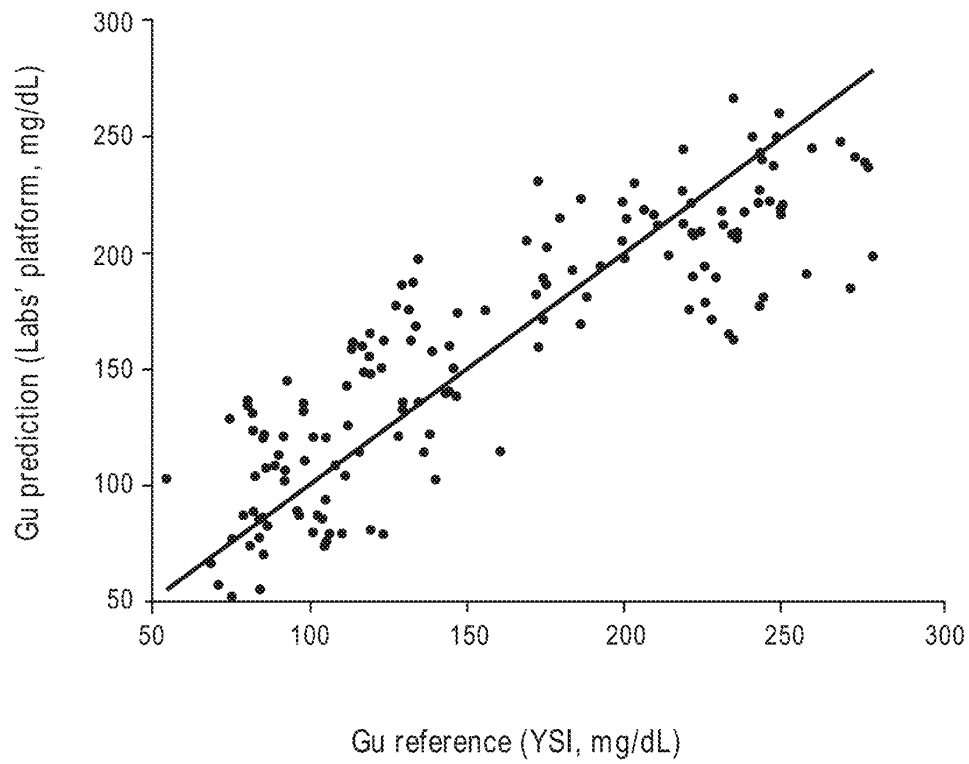


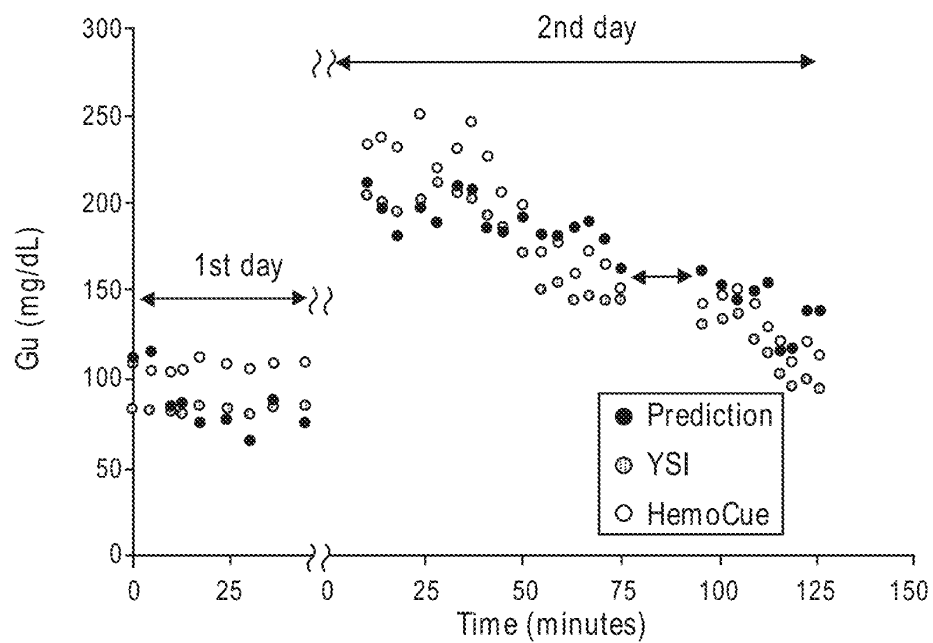
FIG. 20

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**FIG. 21**

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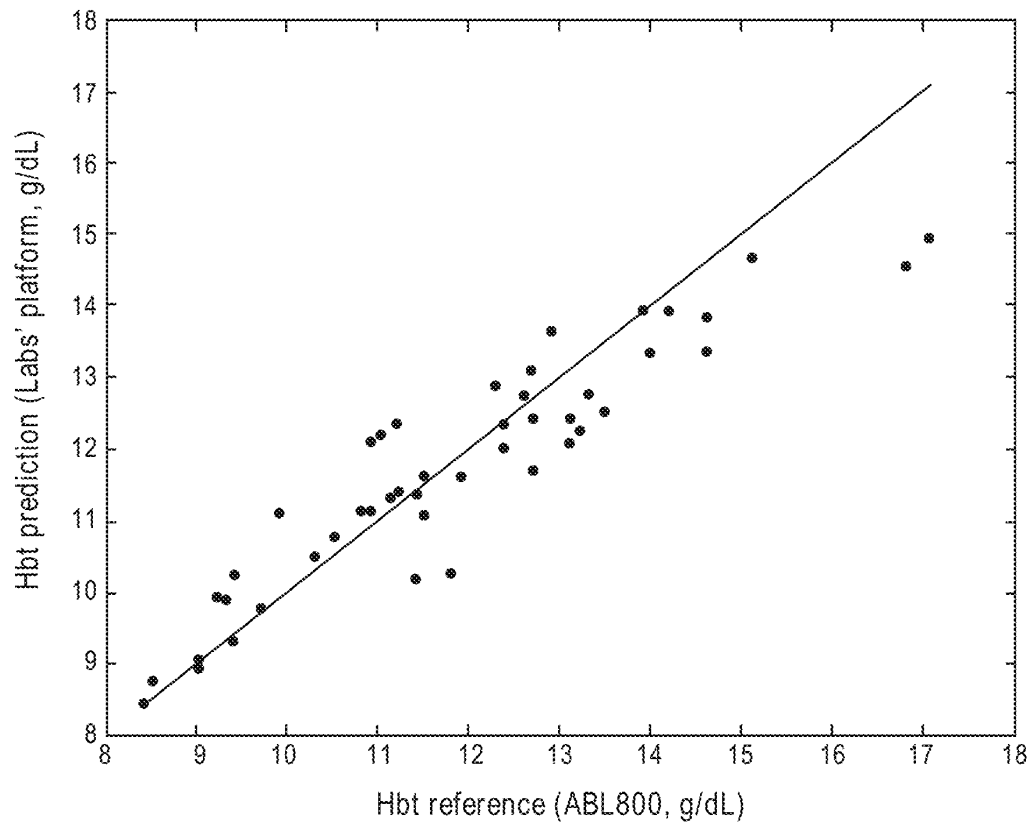


FIG. 22

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USER-WORN DEVICE FOR NONINVASIVELY MEASURING A PHYSIOLOGICAL PARAMETER OF A USER

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/834,538, filed Mar. 30, 2020, which is a continuation of U.S. patent application Ser. No. 16/725,292, filed Dec. 23, 2019, which is a continuation of U.S. patent application Ser. No. 16/534,949, filed Aug. 7, 2019, which is a continuation of U.S. patent application Ser. No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Ser. No. 29/323,409 filed Aug. 25, 2008 and Ser. No. 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. patent applications:

App. No.	Filing Date	Title
12/497,528	Jul. 2, 2009	Noise Shielding for Noninvasive Device
12/497,523	Jul. 2, 2009	Contoured Protrusion for Improving Spectroscopic Measurement of Blood Constituents
12/497,506	Jul. 2, 2009	Heat Sink for Noninvasive Medical Sensor
12/534,812	Aug. 3, 2009	Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents

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-continued

App. No.	Filing Date	Title
12/534,823	Aug. 3, 2009	Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents
12/534,825	Aug. 3, 2009	Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents

The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal (s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the non-invasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from

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said optical source after attenuation by the tissue of the measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the

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signals from the plurality of detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at

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sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. 1 illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. 2A-2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. 1, according to embodiments of the disclosure;

FIGS. 3A-3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. 3D illustrates a side view of another example noninvasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. 3E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. 3F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. 4A through 4C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

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FIG. 5 illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

FIGS. 6A through 6D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. 6E illustrates an example sensor incorporating the protrusion of FIGS. 6A through 6D, according to an embodiment of the disclosure;

FIGS. 7A through 7B illustrate example arrangements of conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIGS. 8A through 8D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIG. 9 shows example comparative results obtained by an embodiment of a sensor;

FIGS. 10A and 10B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. 11A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 12A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. 12B through 12D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. 12E through 12H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. 13 illustrates an example multi-stream operation of the system of FIG. 1, according to an embodiment of the disclosure;

FIG. 14A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion of FIG. 14A;

FIGS. 14C through 14E illustrate embodiments of a detector submount;

FIGS. 14F through 14H illustrate embodiment of portions of a detector shell;

FIG. 14I illustrates a cutaway view of an embodiment of a sensor;

FIGS. 15A through 15F illustrate embodiments of sensors that include heat sink features;

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. 15I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

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FIG. 15J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. 15I;

FIG. 15K shows different architectures and layouts for various embodiments of a sensor and its detectors;

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors;

FIG. 17 illustrates an exploded view of certain components of an example sensor; and

FIGS. 18 through 22 illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic,

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helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of non-invasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metalized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can

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be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that, in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter

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may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. 1 illustrates an example of a data collection system **100**. In certain embodiments, the data collection system **100** noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system **100** can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system **100** can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system **100** can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm²-5 mm² (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system **100** can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system **100** can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system **100** can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system **100** can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site **102**. The measurement site **102** can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a

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finger measurement site **102**. However, the features of the embodiments disclosed herein can be used with other measurement sites **102**.

In the depicted embodiment, the system **100** includes an optional tissue thickness adjuster or tissue shaper **105**, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper **105** is a flat or substantially flat surface that can be positioned proximate the measurement site **102** and that can apply sufficient pressure to cause the tissue of the measurement site **102** to be flat or substantially flat. In other embodiments, the tissue shaper **105** is a convex or substantially convex surface with respect to the measurement site **102**. Many other configurations of the tissue shaper **105** are possible. Advantageously, in certain embodiments, the tissue shaper **105** reduces thickness of the measurement site **102** while preventing or reducing occlusion at the measurement site **102**. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system **100** shown also includes an optional noise shield **103**. In an embodiment, the noise shield **103** can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site **102** to one or more detectors **106** (described below). For example, the noise shield **103** can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor **101** or electrically grounded. In an embodiment where the noise shield **103** includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site **102** is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system **100** can be used on a person's non-dominant hand or arm.

The data collection system **100** can include a sensor **101** (or multiple sensors) that is coupled to a processing device or physiological monitor **109**. In an embodiment, the sensor **101** and the monitor **109** are integrated together into a single unit. In another embodiment, the sensor **101** and the monitor **109** are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor **101** and monitor **109** can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor **101** and the monitor **109** will now be further described.

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In the depicted embodiment shown in FIG. 1, the sensor **101** includes an emitter **104**, a tissue shaper **105**, a set of detectors **106**, and a front-end interface **108**. The emitter **104** can serve as the source of optical radiation transmitted towards measurement site **102**. As will be described in further detail below, the emitter **104** can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **104** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter **104** is used as a point optical source, and thus, the one or more optical sources of the emitter **104** can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters **104** can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters **104** can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters **104**.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter **104** of the data collection system **100** can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter **104** can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter **104** can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter **104** can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter **104** can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter **104** can emit optical radiation across other spectra for other analytes. In particular, the emitter **104** can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter **104** can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about

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1665 nm. In another embodiment, the emitter **104** can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, the emitter **104** can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system **100** can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter **104** can include sets of light-emitting diodes (LEDs) as its optical source. The emitter **104** can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter **104** can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter **104** can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter **104** can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter **104** can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO₂), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter **104** can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site **102**.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter **104** can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter **104** to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system **100** also includes a driver **111** that drives the emitter **104**. The driver **111** can be a circuit or the like that is controlled by the monitor **109**. For example, the driver **111** can provide pulses of current to the emitter **104**. In an embodiment, the driver **111** drives the emitter **104** in a progressive fashion, such as in an alternating manner. The driver **111** can drive the emitter **104** with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from

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about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

The driver **111** can be synchronized with other parts of the sensor **101** and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter **104**. In some embodiments, the driver **111** is capable of driving the emitter **104** to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors **106** capture and measure light from the measurement site **102**. For example, the detectors **106** can capture and measure light transmitted from the emitter **104** that has been attenuated or reflected from the tissue in the measurement site **102**. The detectors **106** can output a detector signal **107** responsive to the light captured or measured. The detectors **106** can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors **106** can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors **106**. That is, some of the detectors **106** can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter **104**. However, according to an embodiment, at least some of the detectors **106** can have a different path length from the emitter **104** relative to other of the detectors **106**. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors **106**. In some embodiments, the detectors **106** may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface **108** provides an interface that adapts the output of the detectors **106**, which is responsive to desired physiological parameters. For example, the front end interface **108** can adapt a signal **107** received from one or more of the detectors **106** into a form that can be processed by the monitor **109**, for example, by a signal processor **110** in the monitor **109**. The front end interface **108** can have its components assembled in the sensor **101**, in the monitor **109**, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface **108** can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface **108** can be coupled to the detectors **106** and to the signal processor **110** using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface **108** can also be at least partially integrated with various components, such as the detectors **106**. For example, the front end interface **108** can include one or more integrated circuits that are on the same circuit board as the detectors **106**. Other configurations can also be used.

The front end interface **108** can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor **109**), such as a sigma-delta ADC. A transimpedance-based front end interface **108** can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface **108** can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface **108**

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can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter **104**.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by the signal processor **110** of the monitor **109**. Each channel can correspond to a signal output from a detector **106**.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface **108**. For example, the output of a transimpedance-based front end interface **108** can be output to a PGA that is coupled with an ADC in the monitor **109**. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors **106**. Alternatively, the PGA and ADC components can be integrated with the transimpedance-based front end interface **108** in the sensor **101**.

In another embodiment, the front end interface **108** can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface **108** can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface **108** can be useful because it can provide a digital signal to the signal processor **110** in the monitor **109**.

As shown in FIG. 1, the monitor **109** can include the signal processor **110** and a user interface, such as a display **112**. The monitor **109** can also include optional outputs alone or in combination with the display **112**, such as a storage device **114** and a network interface **116**. In an embodiment, the signal processor **110** includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors **106**. The signal processor **110** can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor **110** can provide various signals that control the operation of the sensor **101**. For example, the signal processor **110** can provide an emitter control signal to the driver **111**. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter **104**. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter **104** to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface **108** is used, the control signal from the signal processor **110** can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory **113** can be included in the front-end interface **108** and/or in the signal processor **110**. This memory **113** can serve as a buffer or storage location for the front-end interface **108** and/or the signal processor **110**, among other uses.

The user interface **112** can provide an output, e.g., on a display, for presentation to a user of the data collection system **100**. The user interface **112** can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface **112** can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface **112** can include a flip screen, a screen that can be moved from one side to another on the monitor **109**, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data

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collection system **100** can be provided without a user interface **112** and can simply provide an output signal to a separate display or system.

A storage device **114** and a network interface **116** represent other optional output connections that can be included in the monitor **109**. The storage device **114** can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device **114**, which can be executed by the signal processor **110** or another processor of the monitor **109**. The network interface **116** can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor **109** to communicate and share data with other devices. The monitor **109** can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface **112**, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system **100** can include various other components or can be configured in different ways. For example, the sensor **101** can have both the emitter **104** and detectors **106** on the same side of the measurement site **102** and use reflectance to measure analytes. The data collection system **100** can also include a sensor that measures the power of light emitted from the emitter **104**.

FIGS. 2A through 2D illustrate example monitoring devices **200** in which the data collection system **100** can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices **200** shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system **100**. In addition, certain of the features of the monitoring devices **200** shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices **200** shown.

Referring specifically to FIG. 2A, an example monitoring device **200A** is shown, in which a sensor **201a** and a monitor **209a** are integrated into a single unit. The monitoring device **200A** shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor **201a** includes an emitter shell **204a** and a detector shell **206a**. The depicted embodiment of the monitoring device **200A** also includes various control buttons **208a** and a display **210a**.

The sensor **201a** can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector **106** by forcing light back into the sensor **201a**. Pads in the emitter shell **204a** and the detector shell **206a** can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell **204a** and the detector shell **206a** can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor **201a**.

In some embodiments, some or all portions of the emitter shell **204a** and/or detector shell **206a** can be detachable and/or disposable. For example, some or all portions of the

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shells **204a** and **206a** can be removable pieces. The removability of the shells **204a** and **206a** can be useful for sanitary purposes or for sizing the sensor **201a** to different patients. The monitor **209a** can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor **201c** to be removably attached to the monitor **209a**.

The monitoring device **200a** also includes optional control buttons **208a** and a display **210a** that can allow the user to control the operation of the device. For example, a user can operate the control buttons **208a** to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons **208a** to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display **210a**, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls **208a** and/or display **210a** can provide functionality for the user to manipulate settings of the monitoring device **200a**, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device **200a** can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. 2B illustrates another example of a monitoring device **200B**. In the depicted embodiment, the monitoring device **200B** includes a finger clip sensor **201b** connected to a monitor **209b** via a cable **212**. In the embodiment shown, the monitor **209b** includes a display **210b**, control buttons **208b** and a power button. Moreover, the monitor **209b** can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor **201b**, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable **212** connecting the sensor **201b** and the monitor **209b** can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable **212** can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor **201b** to the monitor **209b**. Various lengths of the cable **212** can be employed to allow for separation between the sensor **201b** and the monitor **209b**. The cable **212** can be fitted with a connector (male or female) on either end of the cable **212** so that the sensor **201b** and the monitor **209b** can be connected and disconnected from each other. Alternatively, the sensor **201b** and the monitor **209b** can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor **209b** can be attached to the patient. For example, the monitor **209b** can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor **209b** can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable **212** and sensor **201b** to be attached to the monitor **209b**.

The monitor **209b** can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor **209b**

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can include a display **210b** that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor **209b**.

In addition, although a single sensor **201b** with a single monitor **209b** is shown, different combinations of sensors and device pairings can be implemented. For example, multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. 2C illustrates yet another example of monitoring device **200C** that can house the data collection system **100**. Like the monitoring device **200B**, the monitoring device **200C** includes a finger clip sensor **201c** connected to a monitor **209c** via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. 2B. The monitor **209c** can include all of the features of the monitor **200B** described above. For example, the monitor **209c** includes buttons **208c** and a display **210c**. The monitor **209c** shown also includes straps **214c** that allow the monitor **209c** to be attached to a patient's limb or the like.

FIG. 2D illustrates yet another example of monitoring device **200D** that can house the data collection system **100**. Like the monitoring devices **200B** and **200C**, the monitoring device **200D** includes a finger clip sensor **201d** connected to a monitor **209d** via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. 2B. In addition to having some or all of the features described above with respect to FIGS. 2B and 2C, the monitoring device **200D** includes an optional universal serial bus (USB) port **216** and an Ethernet port **218**. The USB port **216** and the Ethernet port **218** can be used, for example, to transfer information between the monitor **209d** and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor **209b**, and perform a variety of other functions. The USB port **216** and the Ethernet port **218** can be included with the other monitoring devices **200A**, **200B**, and **200C** described above.

FIGS. 3A through 3C illustrate more detailed examples of embodiments of a sensor **301a**. The sensor **301a** shown can include all of the features of the sensors **100** and **200** described above.

Referring to FIG. 3A, the sensor **301a** in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure **302a** for receiving a patient's finger. The enclosure **302a** is formed by an upper section or emitter shell **304a**, which is pivotably connected with a lower section or detector shell **306a**. The emitter shell **304a** can be biased with the detector shell **306a** to close together around a pivot point **303a** and thereby sandwich finger tissue between the emitter and detector shells **304a**, **306a**.

In an embodiment, the pivot point **303a** advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells **304a**, **306a** to effectively level the sections when applied to a tissue site. In another embodiment, the sensor **301a** includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell **304a** can position and house various emitter components of the sensor **301a**. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metallicized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell **304a** can also include absorbing opaque mate-

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rial, such as, for example, black or grey colored material, at various areas, such as on one or more flaps 307a, to reduce ambient light entering the sensor 301a.

The detector shell 306a can position and house one or more detector portions of the sensor 301a. The detector shell 306a can be constructed of reflective material, such as white silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. 1). The detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308a, to reduce ambient light entering the sensor 301a.

Referring to FIGS. 3B and 3C, an example of finger bed 310 is shown in the sensor 301b. The finger bed 310 includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

Finger bed 310 can also include an embodiment of a tissue thickness adjuster or protrusion 305. The protrusion 305 includes a measurement site contact area 370 (see FIG. 3C) that can contact body tissue of a measurement site. The protrusion 305 can be removed from or integrated with the finger bed 310. Interchangeable, different shaped protrusions 305 can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. 3C, the contact area 370 of the protrusion 305 can include openings or windows 320, 321, 322, and 323. When light from a measurement site passes through the windows 320, 321, 322, and 323, the light can reach one or more photodetectors (see FIG. 3E). In an embodiment, the windows 320, 321, 322, and 323 mirror specific detector placements layouts such that light can impinge through the protrusion 305 onto the photodetectors. Any number of windows 320, 321, 322, and 323 can be employed in the protrusion 305 to allow light to pass from the measurement site to the photodetectors.

The windows 320, 321, 322, and 323 can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows 320, 321, 322, and 323 can be made from materials, such as plastic or glass. In some embodiments, the windows 320, 321, 322, and 323 can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

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Turning to FIG. 3B, the sensor 301a can also include a shielding 315a, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding 315a is provided in the depicted embodiment below or embedded within the protrusion 305 to reduce noise. The shielding 315a can be constructed from a conductive material, such as copper. The shielding 315a can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows 320, 321, 322, and 323 on an external surface of the protrusion 305 (see FIG. 3C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. 3E).

In some embodiments, the shielding cage for shielding 315a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion 305 (see FIG. 3E). In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion 305 can be selected. In making such determinations, consideration can be made of protrusion's 305 effect on blood flow at the measurement site and mean path length for optical radiation passing through openings 320, 321, 322, and 323. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion 305 can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area 370 to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion 305 can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area 370. The contact area 370 can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion 305 can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion 305 and the contact area 370 can include a combination of materials with various characteristics.

The contact area 370 serves as a contact surface for the measurement site. For example, in some embodiments, the contact area 370 can be shaped for contact with a patient's finger. Accordingly, the contact area 370 can be sized and shaped for different sizes of fingers. The contact area 370 can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example,

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the contact area **370** can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. **5** provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

Referring to FIG. **5**, a plot **500** is shown that illustrates examples of effects of embodiments of the protrusion **305** on the SNR at various wavelengths of light. As described above, the protrusion **305** can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion **305** can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I = I_0 * e^{-m * b * c}$, where I_0 is the initial power of light being transmitted, m is the path length traveled by the light, and the component “ $b * c$ ” corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1} . Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I = I_0 * e^{(-20 * 0.7)}$.

In an embodiment where the protrusion **305** is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box **510**). This results in a new transmittance, $I_1 = I_0 * e^{(-16.6 * 0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot **500** of FIG. **5**. The plot **500** illustrates potential effects of the protrusion **305** on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6 * 0.7) / e^{(-20 * 0.7)}}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1} . The plot **500** also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. **3A** through **3C**, an example heat sink **350a** is also shown. The heat sink **350a** can be attached to, or protrude from an outer surface of, the sensor **301a**, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor **301a** in certain embodiments, the heat sink **350a** can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. **1**) generate sufficient heat that inclusion of the heat sink **350a** can advantageously allow the sensor **301a** to remain safely cooled. The heat sink **350a** can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell **304a** can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink **350a** includes metalized plastic. The metalized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink **350a** can include a thermally conductive liquid crystalline

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polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, R.I. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink **350a** provides improved heat transfer properties when the sensor **301a** is active for short intervals of less than a full day's use. In an embodiment, the heat sink **350a** can advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink **350a** can be selected that performs effectively in shorter or longer intervals.

Moreover, the heat sink **350a** can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink **350a** is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink **350a** shown includes fins **351a** (see FIG. **3A**).

An alternative shape of a sensor **301b** and heat sink **350b** is shown in FIG. **3D**. The sensor **301b** can include some or all of the features of the sensor **301a**. For example, the sensor **301b** includes an enclosure **302b** formed by an emitter shell **304b** and a detector shell **306b**, pivotably connected about a pivot **303a**. The emitter shell **304b** can also include absorbing opaque material on one or more flaps **307b**, and the detector shell **306a** can also include absorbing opaque material at various areas, such as lower area **308b**.

However, the shape of the sensor **301b** is different in this embodiment. In particular, the heat sink **350b** includes comb protrusions **351b**. The comb protrusions **351b** are exposed to the air in a similar manner to the fins **351a** of the heat sink **350a**, thereby facilitating efficient cooling of the sensor **301b**.

FIG. **3E** illustrates a more detailed example of a detector shell **306b** of the sensor **301b**. The features described with respect to the detector shell **306b** can also be used with the detector shell **306a** of the sensor **301a**.

As shown, the detector shell **306b** includes detectors **316**. The detectors **316** can have a predetermined spacing **340** from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors **316** and the emitter discussed above.

In the depicted embodiment, the detector shell **316** can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site **102**). In the detector shell **316**, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell **316** can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. **3E**, the detectors **316** can have a spatial configuration of a grid. However, the detectors **316** can be arranged in other configurations that vary the path length. For example, the detectors **316** can be arranged in a linear array, a logarithmic array, a two-dimensional

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array, a zig-zag pattern, or the like. Furthermore, any number of the detectors 316 can be employed in certain embodiments.

FIG. 3F illustrates another embodiment of a sensor 301f. The sensor 301f can include some or all of the features of the sensor 301a of FIG. 3A described above. For example, the sensor 301f includes an enclosure 302f formed by an upper section or emitter shell 304f, which is pivotably connected with a lower section or detector shell 306f around a pivot point 303f. The emitter shell 304f can also include absorbing opaque material on various areas, such as on one or more flaps 307f, to reduce ambient light entering the sensor 301f. The detector shell 306f can also include absorbing opaque material at various areas, such as a lower area 308f. The sensor 301f also includes a heat sink 350f, which includes fins 351f.

In addition to these features, the sensor 301f includes a flex circuit cover 360, which can be made of plastic or another suitable material. The flex circuit cover 360 can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell 304f to the detector shell 306f. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. 46 and associated description, which is hereby specifically incorporated by reference). The flex circuit cover 360 is shown in more detail below in FIG. 17.

In addition, sensors 301a-f has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. 4A through 4C illustrate example arrangements of a protrusion 405, which is an embodiment of the protrusion 305 described above. In an embodiment, the protrusion 405 can include a measurement site contact area 470. The measurement site contact area 470 can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion 405 can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion 405 can have a length 400, a width 410, and a height 430. The length 400 can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width 410 can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area 470 can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site. The measurement site contact area 470 can be other shapes that reduce or even minimize air between the protrusion 405 and/or the measurement site. Additionally, the surface pattern of the measurement site contact area 470 can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. 4A and 4C, openings or windows 420, 421, 422, and 423 can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows 420, 421, 422, and 423 can be of non-uniform shapes and sizes. As shown, the windows 420, 421, 422, and 423 can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of

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arranging the windows 420, 421, 422, and 423 are possible. For example, the windows 420, 421, 422, and 423 can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows 420, 421, 422, and 423 can be placed at different heights with respect to the finger bed 310 of FIG. 3. The windows 420, 421, 422, and 423 can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

FIGS. 6A through 6D illustrate another embodiment of a protrusion 605 that can be used as the tissue shaper 105 described above or in place of the protrusions 305, 405 described above. The depicted protrusion 605 is a partially cylindrical lens having a partial cylinder 608 and an extension 610. The partial cylinder 608 can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion 605 focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. 6A illustrates a perspective view of the partially cylindrical protrusion 605. FIG. 6B illustrates a front elevation view of the partially cylindrical protrusion 605. FIG. 6C illustrates a side view of the partially cylindrical protrusion 605. FIG. 6D illustrates a top view of the partially cylindrical protrusion 605.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion 605 over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion 605 penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion 605 can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion 605 can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. 14). If fewer or smaller photodiodes are used, the partially cylindrical protrusion 605 can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion 605 can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. 6C, the overall height of the partially cylindrical protrusion 605 (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion 605 to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion 605 can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion 605 is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. 6D, the width of the partially cylindrical protrusion 605 (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration

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of the partially cylindrical protrusion **605** into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the width of the partially cylindrical protrusion **605** can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion **605** could be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially cylindrical protrusion **605** can be expressed as:

$$f = \frac{R}{n-1},$$

where R is the radius of curvature of the partial cylinder **608** and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion **605** can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion **605** having a material with a higher index of refraction such as nSF11 glass (e.g., $n=1.75$ at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion **605** can be chosen to improve or optimize the light focusing properties of the protrusion **605**. A plastic partially cylindrical protrusion **605** could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion **605**.

Placing a photodiode at a given distance below the partially cylindrical protrusion **605** can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. 14). Different sizes of the partially cylindrical protrusion **605** can use different sizes of photodiodes. The extension **610** added onto the bottom of the partial cylinder **608** is used in certain embodiments to increase the height of the partially cylindrical protrusion **605**. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion **605**. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension **610** can also further facilitate the protrusion **605** increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension **610** can be omitted.

FIG. 6E illustrates another view of the sensor **301f** of FIG. 3F, which includes an embodiment of a partially cylindrical protrusion **605b**. Like the sensor **301A** shown in FIGS. 3B and 3C, the sensor **301f** includes a finger bed **310f**. The finger bed **310f** includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger

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bed **310f** also includes the ridges or channels **314** described above with respect to FIGS. 3B and 3C.

The example of finger bed **310f** shown also includes the protrusion **605b**, which includes the features of the protrusion **605** described above. In addition, the protrusion **605b** also includes chamfered edges **607** on each end to provide a more comfortable surface for a finger to slide across (see also FIG. 14D). In another embodiment, the protrusion **605b** could instead include a single chamfered edge **607** proximal to the ridges **314**. In another embodiment, one or both of the chamfered edges **607** could be rounded.

The protrusion **605b** also includes a measurement site contact area **670** that can contact body tissue of a measurement site. The protrusion **605b** can be removed from or integrated with the finger bed **310f**. Interchangeable, differently shaped protrusions **605b** can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. 7A and 7B illustrate block diagrams of sensors **701** that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors **701** can be implemented with any of the sensors **101**, **201**, **301** described above. Although not shown, the partially cylindrical protrusion **605** of FIG. 6 can also be used with the sensors **701** in certain embodiments.

For example, referring specifically to FIG. 7A, the sensor **701a** includes an emitter housing **704a** and a detector housing **706**. The emitter housing **704a** includes LEDs **104**. The detector housing **706a** includes a tissue bed **710a** with an opening or window **703a**, the conductive glass **730a**, and one or more photodiodes for detectors **106** provided on a submount **707a**.

During operation, a finger **102** can be placed on the tissue bed **710a** and optical radiation can be emitted from the LEDs **104**. Light can then be attenuated as it passes through or is reflected from the tissue of the finger **102**. The attenuated light can then pass through the opening **703a** in the tissue bed **710a**. Based on the received light, the detectors **106** can provide a detector signal **107**, for example, to the front end interface **108** (see FIG. 1).

In the depicted embodiment, the conductive glass **730** is provided in the opening **703**. The conductive glass **730** can thus not only permit light from the finger to pass to the detectors **106**, but it can also supplement the shielding of the detectors **106** from noise. The conductive glass **730** can include a stack or set of layers. In FIG. 7A, the conductive glass **730a** is shown having a glass layer **731** proximate the finger **102** and a conductive layer **733** electrically coupled to the shielding **790a**.

In an embodiment, the conductive glass **730a** can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure **790a**, the conductive glass **730a** can be electrically coupled to the shielding enclosure **790a**. The conductive glass **730a** can be electrically coupled to the shielding **704a** based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure **790a** can be provided to encompass the detectors **106** to reduce or prevent noise. For example, the shielding enclosure **790a** can be constructed from a conductive material, such as copper, in the form of a metal cage. The shielding or enclosure can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

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In some embodiments, the shielding enclosure **790a** can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790a** can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

Referring to FIG. 7B, another block diagram of an example sensor **701b** is shown. A tissue bed **710b** of the sensor **701b** includes a protrusion **705b**, which is in the form of a convex bump. The protrusion **705b** can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion **705b** includes a contact area **370** that comes in contact with the finger **102** and which can include one or more openings **703b**. One or more components of conductive glass **730b** can be provided in the openings **703**. For example, in an embodiment, each of the openings **703** can include a separate window of the conductive glass **730b**. In an embodiment, a single piece of the conductive glass **730b** can be used for some or all of the openings **703b**. The conductive glass **730b** is smaller than the conductive glass **730a** in this particular embodiment.

A shielding enclosure **790b** is also provided, which can have all the features of the shielding enclosure **790a**. The shielding enclosure **790b** is smaller than the shielding enclosure **790a**; however, a variety of sizes can be selected for the shielding enclosures **790**.

In some embodiments, the shielding enclosure **790b** can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790b** can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

FIGS. 8A through 8D illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors **701a**, **701b**. As shown in the perspective view of FIG. 8A and side view of FIG. 8B, the conductive glass **730** includes the electrically conductive material **733** described above as a coating on the glass layer **731** described above to form a stack. In an embodiment where the electrically conductive material **733** includes indium tin oxide, surface resistivity of the electrically conductive material **733** can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material **733**.

Although the conductive material **733** is shown spread over the surface of the glass layer **731**, the conductive material **733** can be patterned or provided on selected portions of the glass layer **731**. Furthermore, the conductive material **733** can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. 8C, a side view of a conductive glass **830a** is shown to illustrate an embodiment where the electrically conductive material **733** is provided as an internal layer between two glass layers **731**, **835**. Various combinations of integrating electrically conductive material **733** with glass

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are possible. For example, the electrically conductive material **733** can be a layer within a stack of layers. This stack of layers can include one or more layers of glass **731**, **835**, as well as one or more layers of conductive material **733**. The stack can include other layers of materials to achieve desired characteristics.

In FIG. 8D, a bottom perspective view is shown to illustrate an embodiment where a conductive glass **830b** can include conductive material **837** that occupies or covers a portion of a glass layer **839**. This embodiment can be useful, for example, to create individual, shielded windows for detectors **106**, such as those shown in FIG. 3C. The conductive material **837** can be patterned to include an area **838** to allow light to pass to detectors **106** and one or more strips **841** to couple to the shielding **704** of FIG. 7.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. 9 depicts an example graph **900** that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. 7 and 8. The graph **900** depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line **915** on the graph **900** illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line **920** on the graph **900** demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line **925** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line **930** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. 10A through 10B illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. 10A, a graph **1000** depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above included separate windows for four (4) detectors **106**. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols **1030-1033** illustrate the

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noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. 10B, a graph 1050 depicts a noise floor for frequencies of noise 1070 for an embodiment in which the sensor included separate openings for four (4) detectors 106 and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols 1080-1083 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. 10A.

FIG. 11A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter 104 can include a driver 1105, a thermistor 1120, a set of top-emitting LEDs 1102 for emitting red and/or infrared light, a set of side-emitting LEDs 1104 for emitting near infrared light, and a submount 1106.

The thermistor 1120 can be provided to compensate for temperature variations. For example, the thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement site. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver 1105 can provide pulses of current to the emitter 1104. In an embodiment, the driver 1105 drives the emitter 1104 in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor 110). For example, the driver 1105 can drive the emitter 1104 with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver 1105 can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter 1104. In some embodiments, the driver 1105 is capable of driving the emitter 1104 to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount 1106 provides a support structure in certain embodiments for aligning the top-emitting LEDs 1102 and the side-emitting LEDs 1104 so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount 1106 is also constructed of aluminum nitride (AlN) or beryllium oxide (BEO) for heat dissipation, although other materials or combinations of materials suitable for the submount 1106 can be used.

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FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter 104 may be driven in a progressive fashion to minimize noise and increase SNR of sensor 101. For example, emitter 104 may be driven based on a progression of power/current delivered to LEDs 1102 and 1104.

In some embodiments, emitter 104 may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter 104 may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. 11B shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs 1102. FIG. 11B also shows that emitter 104 may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs 1104. Emitter 104 may be progressively driven at higher power/current. This progression may allow driver circuit 105 to stabilize in its operations, and thus, provide a more stable current/power to LEDs 1102 and 1104.

For example, as shown in FIG. 11B, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs 1102 may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs 1104 (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit 105 to stabilize after operating at higher current/power.

As shown in FIG. 11B, top emitting LEDs 1102 may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs 1102 may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs 502 for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter 104.

Subsequently, side emitting LEDs 1104 may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site 102 to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment, the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the

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current needed to drive side emitting LEDs **1104**. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter **104**.

As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit **1105** to stabilize its power delivery to LEDs **1102** and **1104**. Driver circuit **1105** may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to allow for stabilization of driver circuit **1105**. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system **100**. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit **1105** may monitor temperatures of the LEDs **1102** and **1104** using the thermistor **1120** and adjust the output of LEDs **1102** and **1104** accordingly. Such a temperature may be used to help sensor **101** correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter **104** can include components mounted on a substrate **1108** and on submount **1106**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**. Side emitting LEDs **1104** may be mounted on submount **1106**. As noted, side-emitting LEDs **1104** may be included in emitter **104** for emitting near infrared light.

As also shown, the sensor of FIG. 11C may include a thermistor **1120**. As noted, the thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter **104** may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter **104** that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter **104** can include components mounted on a substrate **1108**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**.

As also shown, the emitter of FIG. 11D may include a thermistor **1120**. The thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** due to heating.

FIG. 12A illustrates a detector submount **1200** having photodiode detectors that are arranged in a grid pattern on the detector submount **1200** to capture light at different

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quadrants from a measurement site. One detector submount **1200** can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount **1200**. The detector submount **1200** can also be used with the partially cylindrical protrusion **605** described above with respect to FIG. 6.

The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount **1200** to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors **106** and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site **102**). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. 12B through 12D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors **106**. As shown, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount **1200** to capture light at different quadrants from measurement site **102**.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors **106** may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors **106** may be employed by embodiments of the present disclosure.

For example, as shown in FIG. 12B, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount **1200**. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

In FIG. 12C, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount **1200**, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances $D1 > D2 > D3$). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. 12D, a different substantially grid pattern on submount **1200** of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. 12E through 12H illustrate several embodiments of photodiodes that may be used in detectors **106**. As shown in these figures, a photodiode **1202** of detector **106** may comprise a plurality of active areas **1204**. These active areas

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204 may be coupled together via a common cathode 1206 or anode 1208 in order to provide a larger effective detection area.

In particular, as shown in FIG. 12E, photodiode 1202 may comprise two (2) active areas 1204a and 1204b. In FIG. 12F, photodiode 1202 may comprise four (4) active areas 1204c-f. In FIG. 12G, photodiode 1202 may comprise three (3) active areas 1204g-i. In FIG. 12H, photodiode 1202 may comprise nine (9) active areas 1204j-r. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode 1202.

FIG. 13 illustrates an example multi-stream process 1300. The multi-stream process 1300 can be implemented by the data collection system 100 and/or by any of the sensors described above. As shown, a control signal from a signal processor 1310 controls a driver 1305. In response, an emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302. As described above, in some embodiments, the pulse sequence 1303 is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence 1303 can be greater (or smaller).

In response to the pulse sequence 1300, detectors 1 to n (n being an integer) in a detector 1306 capture optical radiation from the measurement site 1302 and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter 1304. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface 1308 can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor 1310. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter 1304.

The signal processor 1310 can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor 1310 can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

Absorbance $A = m \cdot b \cdot c$, where:

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of $M^{-1} \text{ cm}^{-1}$);

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$$T = I/I_o, \text{ where:}$$

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I is the light intensity measured by the instrument from the measurement site; and

I_o is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A = -\log T$$

Therefore, substituting equations from above:

$$A = -\log(I/I_o)$$

In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I/I_o)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_o), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude than what is achievable by currently available technology.

In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T = e^{-m \cdot b \cdot c}$$

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In terms of light intensity, this equation can also be rewritten as:

$$I/I_o = e^{-m \cdot b \cdot c}$$

Or, at a detector, the measured light (I) can be expressed as:

$$I = I_o \cdot e^{-m \cdot b \cdot c}$$

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $I_1 \dots I_n$ streams of measurements. Assuming each of these detectors have their own path lengths, $b_1 \dots b_n$, from the light source, the measured light intensities can be expressed as:

$$I_n = I_o \cdot e^{-m \cdot b_n \cdot c}$$

The measured light intensities at any two different detectors can be referenced to each other. For example:

$$I_1/I_n = (I_o \cdot e^{-m \cdot b_1 \cdot c}) / (I_o \cdot e^{-m \cdot b_n \cdot c})$$

As can be seen, the terms, I_o , cancel out and, based on exponent algebra, the equation can be rewritten as:

$$I_1/I_n = e^{-m(b_1 - b_n)c}$$

From this equation, the analyte concentration (c) can now be derived from bulk signals $I_1 \dots I_n$ and knowing the respective mean path lengths b_1 and b_n . This scheme also allows for the cancelling out of I_o , and thus, noise generated by the emitter 1304 can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) 1302. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. 14A illustrates an embodiment of a detector submount 1400a positioned beneath the partially cylindrical protrusion 605 of FIG. 6 (or alternatively, the protrusion 605b). The detector submount 1400a includes two rows 1408a of detectors 1410a. The partially cylindrical protrusion 605 can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion 605 can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion 605, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

Applying the partially cylindrical protrusion 605 to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion 605 (see FIG. 14B). This is the example situation illustrated in FIG. 14—two rows 1408a of detectors 1410a

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are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion 605 can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion 605 (or alternatively, the protrusion 605b) that illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors. The protrusion 605 is placed above a detector submount 1400b having one or more detectors 1410b disposed thereon. The submount 1400b can include any number of rows of detectors 1410, although one row is shown.

Light, represented by rays 1420, is emitted from the emitters onto the protrusion 605. These light rays 1420 can be attenuated by body tissue (not shown). When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion 605. The refraction causes the rays 1422 to be focused or substantially focused on the one or more detectors 1410b. Since the light is focused on a smaller area, a sensor including the protrusion 605 can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. 14C illustrates another embodiment of a detector submount 1400c, which can be disposed under the protrusion 605b (or alternatively, the protrusion 605). The detector submount 1400c includes a single row 1408c of detectors 1410c. The detectors are electrically connected to conductors 1412c, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount 1400c is shown positioned under the protrusion 605b in a detector subassembly 1450 illustrated in FIG. 14D. A top-down view of the detector subassembly 1450 is also shown in FIG. 14E. In the detector subassembly 1450, a cylindrical housing 1430 is disposed on the submount 1400c. The cylindrical housing 1430 includes a transparent cover 1432, upon which the protrusion 605b is disposed. Thus, as shown in FIG. 14D, a gap 1434 exists between the detectors 1410c and the protrusion 605b. The height of this gap 1434 can be chosen to increase or maximize the amount of light that impinges on the detectors 1410c.

The cylindrical housing 1430 can be made of metal, plastic, or another suitable material. The transparent cover 1432 can be fabricated from glass or plastic, among other materials. The cylindrical housing 1430 can be attached to the submount 1400c at the same time or substantially the same time as the detectors 1410c to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing 1430 in various embodiments.

In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432) forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c more effectively than cur-

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rently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing 1430 is at least partially made of metal, the cylindrical housing 1430 can provide noise shielding for the detectors 1410c. For example, the cylindrical housing 1430 can be soldered to a ground connection or ground plane on the submount 1400c, which allows the cylindrical housing 1430 to reduce noise. In another embodiment, the transparent cover 1432 can include a conductive material or conductive layer, such as conductive glass or plastic. The transparent cover 1432 can include any of the features of the noise shields 790 described above.

The protrusion 605b includes the chamfered edges 607 described above with respect to FIG. 6E. These chamfered edges 607 can allow a patient to more comfortably slide a finger over the protrusion 605b when inserting the finger into the sensor 301f.

FIG. 14F illustrates a portion of the detector shell 306f, which includes the detectors 1410c on the substrate 1400c. The substrate 1400c is enclosed by a shielding enclosure 1490, which can include the features of the shielding enclosures 790a, 790b described above (see also FIG. 17). The shielding enclosure 1490 can be made of metal. The shielding enclosure 1490 includes a window 1492a above the detectors 1410c, which allows light to be transmitted onto the detectors 1410c.

A noise shield 1403 is disposed above the shielding enclosure 1490. The noise shield 1403, in the depicted embodiment, includes a window 1492a corresponding to the window 1492a. Each of the windows 1492a, 1492b can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows 1492a, 1492b may be selected to have different sizes or shapes from each other.

The noise shield 1403 can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield 1403 extends about three-quarters of the length of the detector shell 306f. In other embodiments, the noise shield 1403 could be smaller or larger. The noise shield 1403 could, for instance, merely cover the detectors 1410c, the submount 1400c, or a portion thereof. The noise shield 1403 also includes a stop 1413 for positioning a measurement site within the sensor 301f. Advantageously, in certain embodiments, the noise shield 1403 can reduce noise caused by light piping.

A thermistor 1470 is also shown. The thermistor 1470 is attached to the submount 1400c and protrudes above the noise shield 1403. As described above, the thermistor 1470 can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors 1410c are not enclosed in the cylindrical housing 1430. In an alternative embodiment, the cylindrical housing 1430 encloses the detectors 1410c and is disposed under the noise shield 1403. In another embodiment, the cylindrical housing 1430 encloses the detectors 1410c and the noise shield 1403 is not used. If both the cylindrical housing 1403 and the noise shield 1403 are used, either or both can have noise shielding features.

FIG. 14G illustrates the detector shell 306f of FIG. 14F, with the finger bed 310f disposed thereon. FIG. 14H illus-

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trates the detector shell 306f of FIG. 14G, with the protrusion 605b disposed in the finger bed 310f.

FIG. 14I illustrates a cutaway view of the sensor 301f. Not all features of the sensor 301f are shown, such as the protrusion 605b. Features shown include the emitter and detector shells 304f, 306f; the flaps 307f; the heat sink 350f and fins 351f; the finger bed 310f; and the noise shield 1403.

In addition to these features, emitters 1404 are depicted in the emitter shell 304f. The emitters 1404 are disposed on a submount 1401, which is connected to a circuit board 1419. The emitters 1404 are also enclosed within a cylindrical housing 1480. The cylindrical housing 1480 can include all of the features of the cylindrical housing 1430 described above. For example, the cylindrical housing 1480 can be made of metal, can be connected to a ground plane of the submount 1401 to provide noise shielding, and can include a transparent cover 1482.

The cylindrical housing 1480 can also protect the emitters 1404 from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing 1480 can provide a gap between the emitters 1404 and the measurement site (not shown), which can allow light from the emitters 1404 to even out or average out before reaching the measurement site.

The heat sink 350f, in addition to including the fins 351f, includes a protuberance 352f that extends down from the fins 351f and contacts the submount 1401. The protuberance 352f can be connected to the submount 1401, for example, with thermal paste or the like. The protuberance 352f can sink heat from the emitters 1404 and dissipate the heat via the fins 351f.

FIGS. 15A and 15B illustrate embodiments of sensor portions 1500A, 1500B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions 1500A, 1500B shown include LED emitters 1504; however, for ease of illustration, the detectors have been omitted. The sensor portions 1500A, 1500B shown can be included, for example, in any of the emitter shells described above.

The LEDs 1504 of the sensor portions 1500A, 1500B are connected to a substrate or submount 1502. The submount 1502 can be used in place of any of the submounts described above. The submount 1502 can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable 1512 is attached to the submount 1502 and includes electrical wiring 1514, such as twisted wires and the like, for communicating with the LEDs 1504. The cable 1512 can correspond to the cables 212 described above.

Although not shown, the cable 1512 can also include electrical connections to a detector. Only a portion of the cable 1512 is shown for clarity. The depicted embodiment of the cable 1512 includes an outer jacket 1510 and a conductive shield 1506 disposed within the outer jacket 1510. The conductive shield 1506 can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield 1506 or a portion of the conductive shield 1506 can be electrically connected to the submount 1502 and can reduce noise in the signal generated by the sensor 1500A, 1500B by reducing RF coupling with the wires 1514. In alternative embodiments, the cable 1512 does not have a conductive shield. For example, the cable 1512

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could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. 15A, in certain embodiments, the conductive shield 1506 can act as a heat sink for the LEDs 1504 by absorbing thermal energy from the LEDs 1504 and/or the submount 1502. An optional heat insulator 1520 in communication with the submount 1502 can also assist with directing heat toward the conductive shield 1506. The heat insulator 1520 can be made of plastic or another suitable material. Advantageously, using the conductive shield 1506 in the cable 1512 as a heat sink can, in certain embodiments, reduce cost for the sensor.

Referring to FIG. 15B, the conductive shield 1506 can be attached to both the submount 1502 and to a heat sink layer 1530 sandwiched between the submount 1502 and the optional insulator 1520. Together, the heat sink layer 1530 and the conductive shield 1506 in the cable 1512 can absorb at least part of the thermal energy from the LEDs and/or the submount 1502.

FIGS. 15C and 15D illustrate implementations of a sensor portion 1500C that includes the heat sink features of the sensor portion 1500A described above with respect to FIG. 15A. The sensor portion 1500C includes the features of the sensor portion 1500A, except that the optional insulator 1520 is not shown. FIG. 15D is a side cutaway view of the sensor portion 1500C that shows the emitters 1504.

The cable 1512 includes the outer jacket 1510 and the conductive shield 1506. The conductive shield 1506 is soldered to the submount 1502, and the solder joint 1561 is shown. In some embodiments, a larger solder joint 1561 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, a cylindrical housing 1580, corresponding to the cylindrical housing 1480 of FIG. 14I, is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15E and 15F illustrate implementations of a sensor portion 1500E that includes the heat sink features of the sensor portion 1500B described above with respect to FIG. 15B. The sensor portion 1500E includes the heat sink layer 1530. The heat sink layer 1530 can be a metal plate, such as a copper plate or the like. The optional insulator 1520 is not shown. FIG. 15F is a side cutaway view of the sensor portion 1500E that shows the emitters 1504.

In the depicted embodiment, the conductive shield 1506 of the cable 1512 is soldered to the heat sink layer 1530 instead of the submount 1502. The solder joint 1565 is shown. In some embodiments, a larger solder joint 1565 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, the cylindrical housing 1580 is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. 1 through 15F. Referring to FIG. 15G, the circuit board 1519 includes a female connector 1575 that mates with a male connector 1577 connected to a daughter board 1587. The daughter board 1587 includes connections to the electrical wiring 1514 of the cable 1512. The connected boards 1519, 1587 are shown in FIG. 15H. Also shown is a hole 1573 that can receive the cylindrical housing 1580 described above.

Advantageously, in certain embodiments, using a daughter board 1587 to connect to the circuit board 1519 can

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enable connections to be made more easily to the circuit board 1519. In addition, using separate boards can be easier to manufacture than a single circuit board 1519 with all connections soldered to the circuit board 1519.

FIG. 15I illustrates an exemplary architecture for front-end interface 108 as a transimpedance-based front-end. As noted, front-end interfaces 108 provide an interface that adapts the output of detectors 106 into a form that can be handled by signal processor 110. As shown in this figure, sensor 101 and front-end interfaces 108 may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor 101 and front end interfaces 108 may comprise multiple components or circuits that are coupled together.

Front-end interfaces 108 may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors 106. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter 900 may be integrated with the transimpedance-based front-end in sensor 101.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector 106, the applicants developed a noise model to assist in configuring front-end 108. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise} = \sqrt{aR + bR^2}, \text{ where:}$$

aR is characteristic of the impedance of the transimpedance amplifier; and

bR^2 is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector 106.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in FIG. 12A) may each comprise four photodiodes. In some embodiments, each detector of four photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. 15J.

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Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the transimpedance amplifiers in this setting may also be set according to the model shown in FIG. 15J.

As yet another alternative, as noted above with respect to FIGS. 12E through 12H, the photodiodes in detectors 106 may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. 15J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary “4 PD per stream” sensor 1502 is shown where detector 106 comprises four photodiodes 1502. The photodiodes 1502 are coupled to a single transimpedance amplifier 1504 to produce an output stream 1506. In this example, the transimpedance amplifier comprises 10 MΩ resistors 1508 and 1510. Thus, output stream 1506 is produced from the four photodiodes (PD) 1502. As shown in the graph of FIG. 15J, the model indicates that resistance values of about 10 MΩ may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary “1 PD per stream” sensor 1512 is also shown in FIG. 15J. In particular, sensor 1512 may comprise a plurality of detectors 106 that each comprises a single photodiode 1514. In addition, as shown for this example configuration, each of photodiodes 1514 may be coupled to respective transimpedance amplifiers 1516, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 MΩ resistors 1518. As also shown in the graph of FIG. 15J, the model illustrates that resistance values of 40 MΩ for resistors 1518 may serve as an alternative to the 4 photodiode per stream architecture of sensor 1502 described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor 1512 may provide enhanced performance because each of transimpedance amplifiers 1516 can be tuned or optimized to its respective photodiodes 1518. In some embodiments, an averaging component 1520 may also be used to help cancel or reduce noise across photodiodes 1518.

For purposes of illustration, FIG. 15K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor 1522 may comprise a “4 PD per stream” architecture on a submount 700 in which each detector 106 comprises four (4) photodiodes 1524. As shown for sensor 1522, the output of each set of four photodiodes 1524 is then aggregated into a single transimpedance amplifier 1526 to produce a signal.

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As another example, a sensor 1528 may comprise a “1 PD per stream” architecture on submount 700 in which each detector 106 comprises four (4) photodiodes 1530. In sensor 1528, each individual photodiode 1530 is coupled to a respective transimpedance amplifier 1532. The output of the amplifiers 1532 may then be aggregated into averaging circuit 1520 to produce a signal.

As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor 1534 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1536 arranged in a linear fashion. Likewise, sensor 1538 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1540 arranged in a linear fashion.

Alternatively, sensor 1542 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1544 arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor 1546 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1548 also arranged in a zig-zag pattern.

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces 108 may be implemented using switched capacitor circuits and any number of front-end interfaces 108 may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface 1000 and signal processor 110. Switched capacitor circuits may be useful in system 100 for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces 108 may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces 108 may require less computational power by signal processor 110 to perform the same amount of decimation to obtain the same SNR.

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors 1600. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors 1600 shown. For instance, the sensors 1600 can be used as the sensors 101 in the system 100 described above with respect to FIG. 1. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors 1600 include an adult/pediatric sensor 1610 for finger placement and a disposable infant/neonate sensor 1602 configured for toe, foot or hand placement. Each sensor 1600 has a tape end 1610 and an opposite connector end 1620 electrically and mechanically interconnected via a flexible coupling 1630. The tape end 1610 attaches an emitter and detector to a tissue site. Although not shown, the tape end 1610 can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

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The sensor signal is communicated via the flexible coupling 1630 to the connector end 1620. The connector end 1620 can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. 2A through 2D. Alternatively, the connector end 1620 can mate directly with the monitor.

FIG. 17 illustrates an exploded view of certain of the components of the sensor 301f described above. A heat sink 1751 and a cable 1781 attach to an emitter shell 1704. The emitter shell attaches to a flap housing 1707. The flap housing 1707 includes a receptacle 1709 to receive a cylindrical housing 1480/1580 (not shown) attached to an emitter submount 1702, which is attached to a circuit board 1719.

A spring 1787 attaches to a detector shell 1706 via pins 1783, 1785, which hold the emitter and detector shells 1704, 1706 together. A support structure 1791 attaches to the detector shell 1706, which provides support for a shielding enclosure 1790. A noise shield 1713 attaches to the shielding enclosure 1790. A detector submount 1700 is disposed inside the shielding enclosure 1790. A finger bed 1710 provides a surface for placement of the patient's finger. Finger bed 1710 may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion 1705 may also be disposed in the finger bed 1710. As shown, finger bed 1710 attaches to the noise shield 1703. The noise shield 1703 may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield 1703 may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield 1703 may also comprise a thermistor 1712. The thermistor 1712 may be helpful in measuring the temperature of a patient's finger. For example, the thermistor 1712 may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor 1712 may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover 1706 attaches to the pins 1783, 1785. Although not shown, a flex circuit can also be provided that connects the circuit board 1719 with the submount 1700 (or a circuit board to which the submount 1700 is connected). A flex circuit protector 1760 may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector 1760 may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector 1760 may be constructed from well known materials, such as a plastic or rubber materials.

FIG. 18 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor 101 were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

FIG. 19 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/

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Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor 101 were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

FIGS. 20 through 22 shows other results that can be obtained by an embodiment of system 100. In FIG. 20, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs and four independent detector streams. As shown, the system 100 obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. 21, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106. As shown, the system 100 was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. 22 relate to total hemoglobin testing with an exemplary sensor 101 of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector channels from detectors 106. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

What is claimed is:

1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit

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light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user;

a protrusion comprising:

- a convex surface extending over the interior surface,
- a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface, and
- a plurality of windows, each of the windows extending across a different one of the openings; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate a measurement of the physiological parameter of the user.

2. The user-worn device of claim 1, wherein the windows comprise glass.

3. The user-worn device of claim 1, wherein the windows comprise plastic.

4. The user-worn device of claim 1 further comprising:

- a network interface configured to wirelessly communicate the measurement of the physiological parameter to at least one of: a mobile phone or a computer network;
- a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurement of the physiological parameter;
- a storage device configured to at least temporarily store at least the measurement; and
- a strap configured to position the user-worn device on the user.

5. The user-worn device of claim 1, wherein the opaque surface is configured to reduce light piping.

6. The user-worn device of claim 1 further comprising:

- at least one wall extending between the interior surface and the protrusion,
- wherein at least the interior surface, the wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities.

7. The user-worn device of claim 1, wherein the physiological parameter comprises at least one of: methemoglobin, total hemoglobin, carboxyhemoglobin, or carbon monoxide.

8. The user-worn device of claim 1, wherein the physiological parameter comprises oxygen or oxygen saturation.

9. The user-worn device of claim 1, wherein the physiological parameter comprises trending information.

10. The user-worn device of claim 1 further comprising a thermistor.

11. The user-worn device of claim 1, wherein the LEDs and the photodiodes are arranged on a same side of the tissue of the user.

12. The user-worn device of claim 1, wherein the one or more processors are further configured to calculate a bulk measurement responsive to a positioning of the user-worn device.

13. The user-worn device of claim 1, wherein, within each of the first and second sets of LEDs, any one LED is positioned within 2 mm to 4 mm of another.

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14. The user-worn device of claim 1, further comprising a third set of LEDs, the third set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength.

15. The user-worn device of claim 1, wherein the four photodiodes comprise first, second, third and fourth photodiodes and wherein the first photodiode and the second photodiode are arranged on the interior surface across from each other on opposite sides of a central point along a first axis, and the third photodiode and the fourth photodiode are arranged across from each other on opposite sides of the central point along a second axis which is different from the first axis.

16. The user-worn device of claim 1, wherein the protrusion further comprises one or more extensions.

17. The user-worn device of claim 16, wherein the one or more extensions surround a perimeter of the convex surface of the protrusion.

18. The user-worn device of claim 1, wherein the protrusion further comprises one or more chamfered edges.

19. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

- a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);
- four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
- a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;
- optically transparent material within each of the openings; and
- one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.

20. The user-worn device of claim 19 further comprising a thermistor.

21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.

22. The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.

23. The user-worn device of claim 22, wherein, within each respective set of at least three LEDs, the LEDs of the set are positioned within 2 mm to 4 mm of each other.

24. The user-worn device of claim 19 further comprising:

- a network interface configured to wirelessly communicate at least the measurements of oxygen saturation to at least one of: a mobile phone or a computer network;
- a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurements of oxygen saturation; and
- a memory device configured to at least temporarily store at least the measurements of oxygen saturation.

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25. The user-worn device of claim 19, wherein the photodiodes comprise first, second, third and fourth photodiodes and wherein the first photodiode and the second photodiode are arranged across from each other on opposite sides of a central point along a first axis, and the third photodiode and the fourth photodiode are arranged across from each other on opposite sides of the central point along a second axis which is different from the first axis.

26. The user-worn device of claim 19, wherein the optically transparent material is glass.

27. The user-worn device of claim 19, wherein the optically transparent material is plastic.

28. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

a thermistor configured to provide a temperature signal;

a protrusion arranged above the interior surface, the protrusion comprising:

a convex surface;

a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and

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a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;

at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;

one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal;

a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;

a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;

a storage device configured to at least temporarily store at least the measurement; and

a strap configured to position the user-worn device on the user.

29. The user-worn device of claim 28, further comprising: a driver configured to energize the first and second sets of LEDs; and

a front-end interface comprising one or more amplifiers and one or more analog to digital converters (ADCs), wherein the front-end interface receives the signals from the photodiodes, the one or more amplifiers amplify the signals and the one or more ADCs convert the signals to digital information, and wherein the processors receive the converted signals.

30. The user-worn device of claim 28, wherein the protrusion further comprises one or more sidewalls extending at least partially around a perimeter of the convex surface.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,912,502 B2
APPLICATION NO. : 17/031407
DATED : February 9, 2021
INVENTOR(S) : Jeroen Poeze et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (63), Page 2, Column 1 at Line 10, Related U.S. Application Data, Change “which is a division” to --which is a continuation--.

Item (63), Page 2, Column 1 at Lines 24-25, Related U.S. Application Data, Change “and a continuation-in-part” to --which is a continuation-in-part--.

In the Specification

In Column 38 at Line 34, Change “15008” to --1500B--.

In Column 38 at Line 65, Change “15008” to --1500B--.

In Column 41 at Line 33, Change “10 MO” to --10 MΩ--.

In Column 41 at Line 36, Change “10 MO” to --10 MΩ--.

In the Claims

In Column 46 at Line 34, In Claim 19, change “one associated with each of” to --one of--.

Signed and Sealed this
Sixth Day of July, 2021



Drew Hirshfeld
*Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office*

U 8115196

**THE UNITED STATES OF AMERICA****TO ALL TO WHOM THESE PRESENTS SHALL COME:****UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

June 02, 2021

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THIS OFFICE OF:****U.S. PATENT: 10,945,648****ISSUE DATE: March 16, 2021****By Authority of the****Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**
SYLVIA HOLLEY
Certifying Officer



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(12) **United States Patent**
Poeze et al.

(10) **Patent No.: US 10,945,648 B2**(45) **Date of Patent: *Mar. 16, 2021**

(54) **USER-WORN DEVICE FOR
NONINVASIVELY MEASURING A
PHYSIOLOGICAL PARAMETER OF A USER**

(71) Applicant: **Masimo Corporation**, Irvine, CA (US)

(72) Inventors: **Jeroen Poeze**, Rancho Santa Margarita, CA (US); **Marcelo Lamago**, Cupertino, CA (US); **Sean Merritt**, Lake Forest, CA (US); **Cristiano Dalvi**, Lake Forest, CA (US); **Hung Vo**, Fountain Valley, CA (US); **Johannes Bruinsma**, Opeinde (NL); **Ferdyan Lesmana**, Irvine, CA (US); **Massi Joe E. Kiani**, Laguna Niguel, CA (US); **Greg Olsen**, Lake Forest, CA (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **17/031,316**

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A61B 5/1455 (2006.01)
A61B 5/145 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
CPC **A61B 5/1455** (2013.01); **A61B 5/14532** (2013.01); **A61B 5/14546** (2013.01); (Continued)

(58) **Field of Classification Search**
CPC . A61B 5/1455; A61B 5/14546; A61B 5/6838; A61B 5/6816; A61B 5/6829; (Continued)

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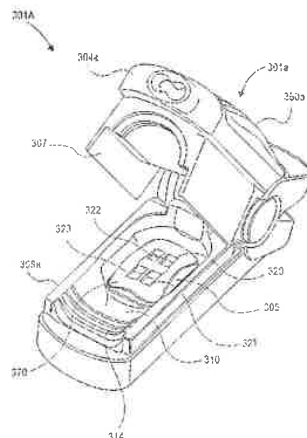
Primary Examiner — Chu Chuan Liu

(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson & Bear LLP

(57) **ABSTRACT**

The present disclosure relates to noninvasive methods, devices, and systems for measuring various blood constituents or analytes, such as glucose. In an embodiment, a light source comprises LEDs and super-luminescent LEDs. The light source emits light at least wavelengths of about 1610 nm, about 1640 nm, and about 1665 nm. In an embodiment, the detector comprises a plurality of photodetectors arranged in a special geometry comprising one of a substantially linear substantially equal spaced geometry, a substantially linear substantially non-equal spaced geometry, and a substantially grid geometry.

30 Claims, 65 Drawing Sheets



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Related U.S. Application Data

- No. 16/725,292, filed on Dec. 23, 2019, now Pat. No. 10,624,564, which is a continuation of application No. 16/534,949, filed on Aug. 7, 2019, now Pat. No. 10,588,553, which is a continuation of application No. 16/409,515, filed on May 10, 2019, now Pat. No. 10,376,191, which is a continuation of application No. 16/261,326, filed on Jan. 29, 2019, now Pat. No. 10,292,628, which is a continuation of application No. 16/212,537, filed on Dec. 6, 2018, now Pat. No. 10,258,266, which is a division of application No. 14/981,290, filed on Dec. 28, 2015, now Pat. No. 10,335,068, which is a continuation of application No. 12/829,352, filed on Jul. 1, 2010, now Pat. No. 9,277,880, which is a continuation of application No. 12/534,827, filed on Aug. 3, 2009, now abandoned, and a continuation-in-part of application No. 12/497,528, filed on Jul. 2, 2009, now Pat. No. 8,577,431, which is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516, and a continuation-in-part of application No. 12/497,523, filed on Jul. 2, 2009, now Pat. No. 8,437,825, said application No. 12/497,523 is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516.
- (60) Provisional application No. 61/086,060, filed on Aug. 4, 2008, provisional application No. 61/086,108, filed on Aug. 4, 2008, provisional application No. 61/086,063, filed on Aug. 4, 2008, provisional application No. 61/086,057, filed on Aug. 4, 2008, provisional application No. 61/091,732, filed on Aug. 25, 2008, provisional application No. 61/078,228, filed on Jul. 3, 2008, provisional application No. 61/078,207, filed on Jul. 3, 2008.
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- (58) **Field of Classification Search**
CPC . A61B 5/6843; A61B 5/6826; A61B 5/14551; A61B 5/14552; A61B 5/14532; A61B 2562/046; A61B 2562/04; A61B 2562/0233; A61B 2562/146
See application file for complete search history.
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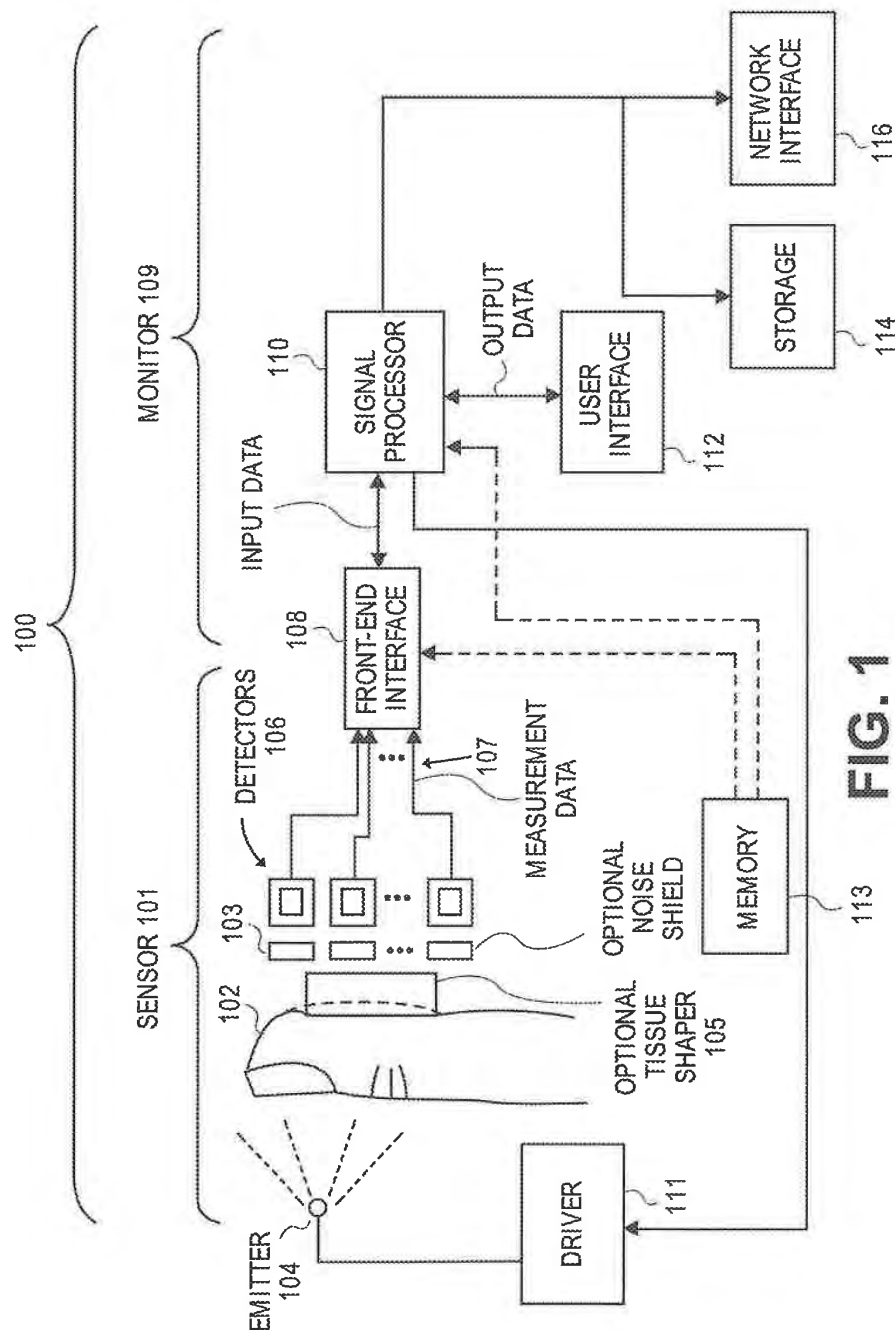
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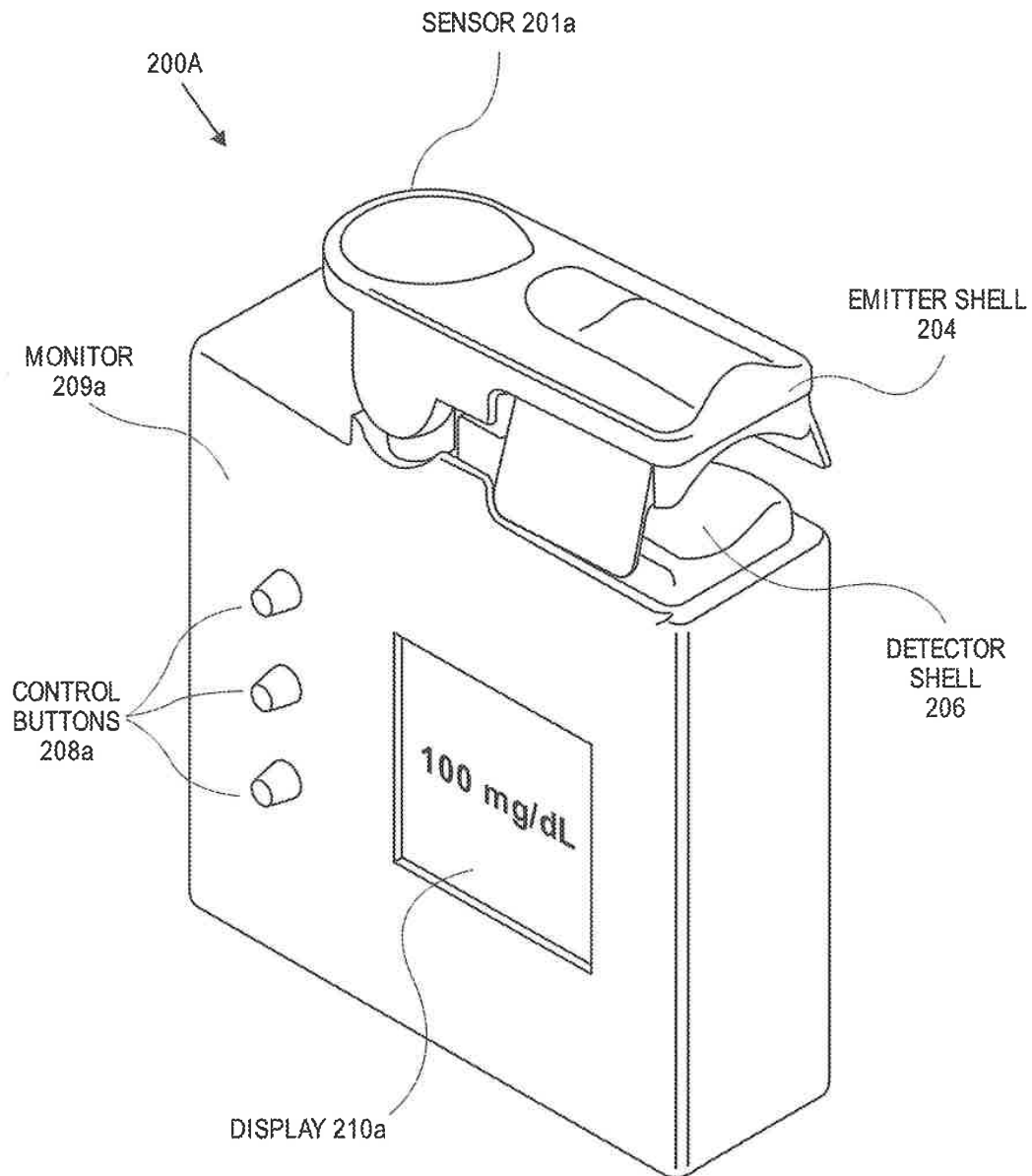


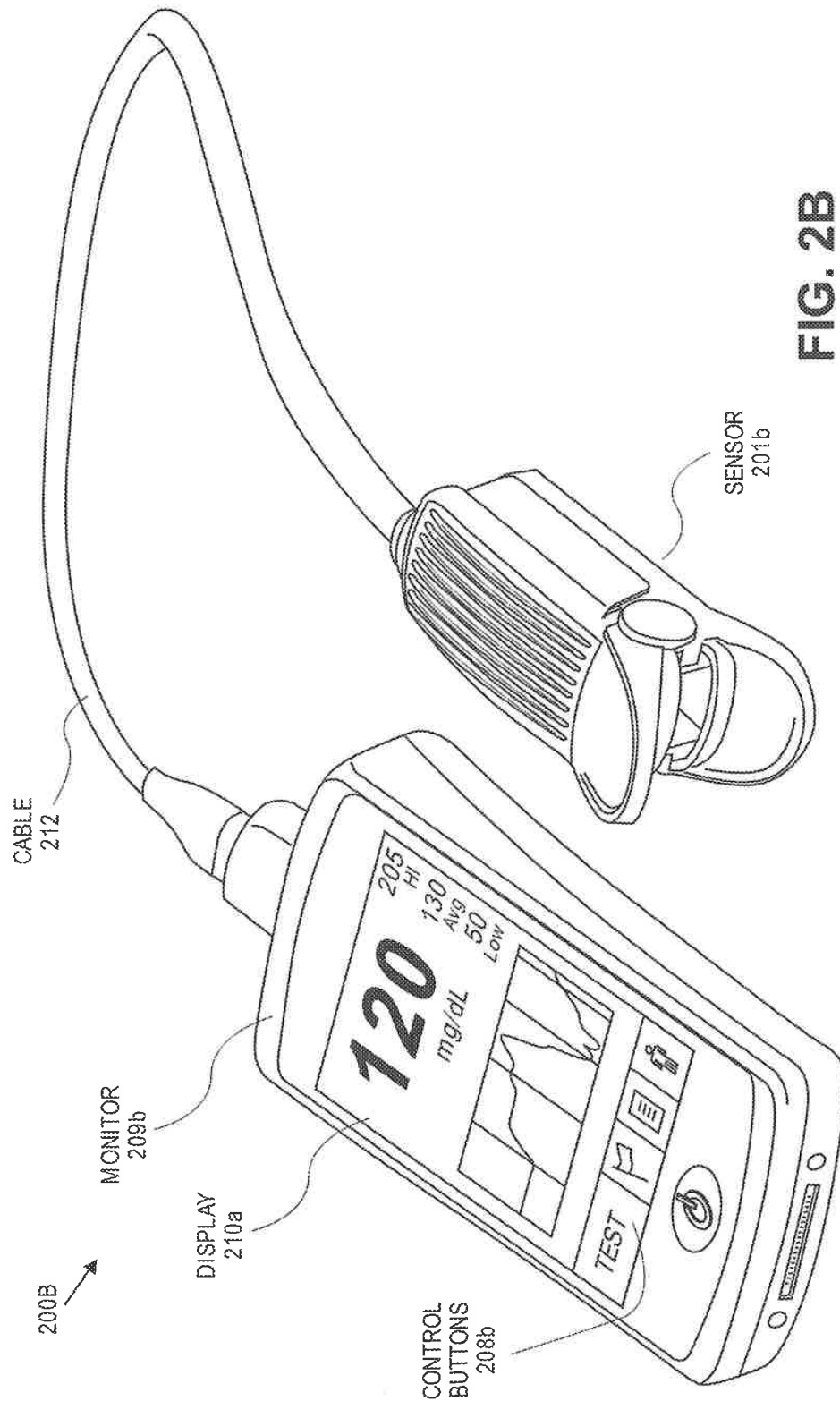
FIG. 2A

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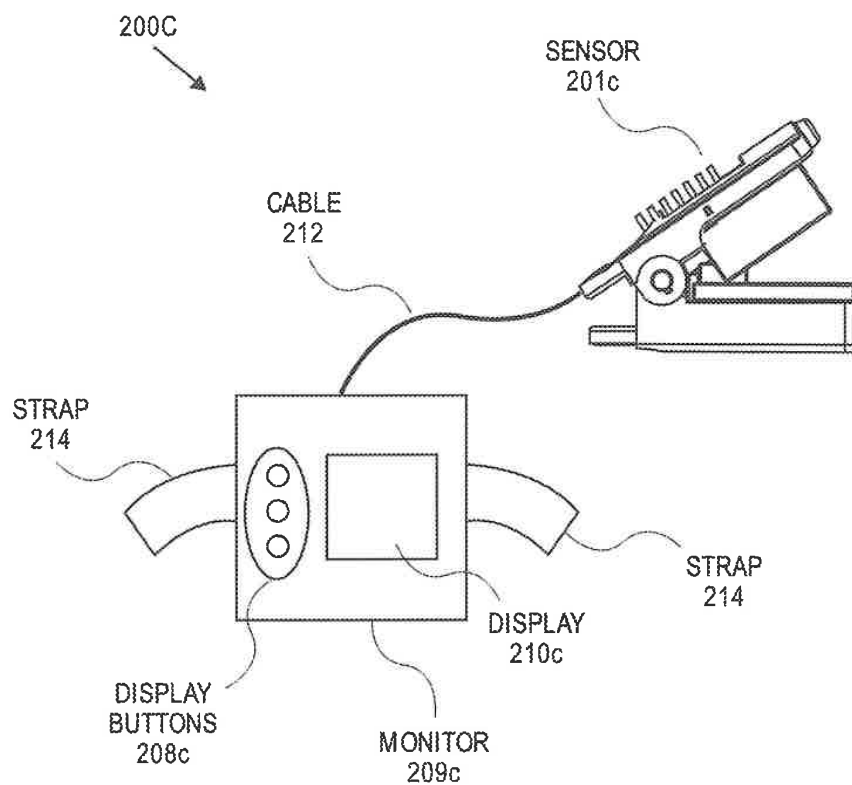


FIG. 2C

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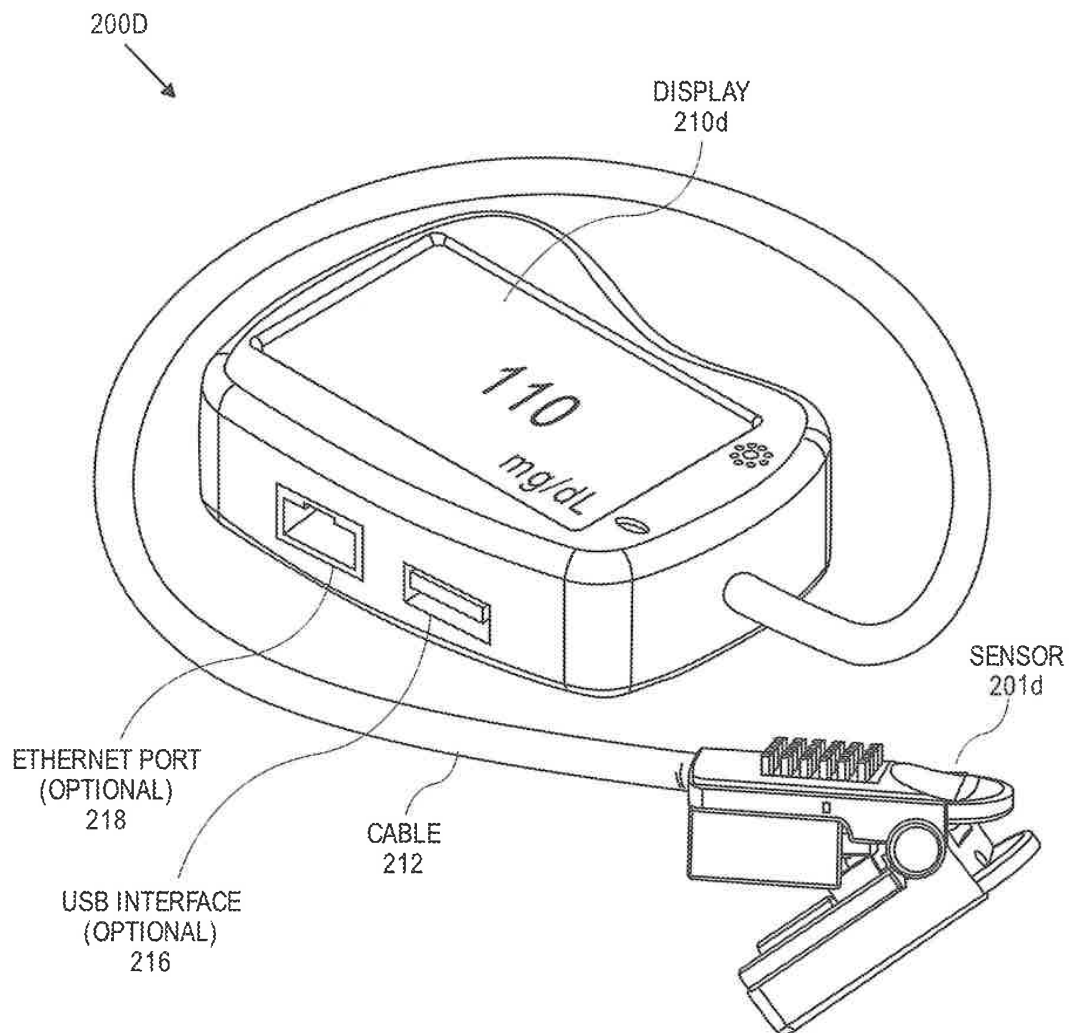


FIG. 2D

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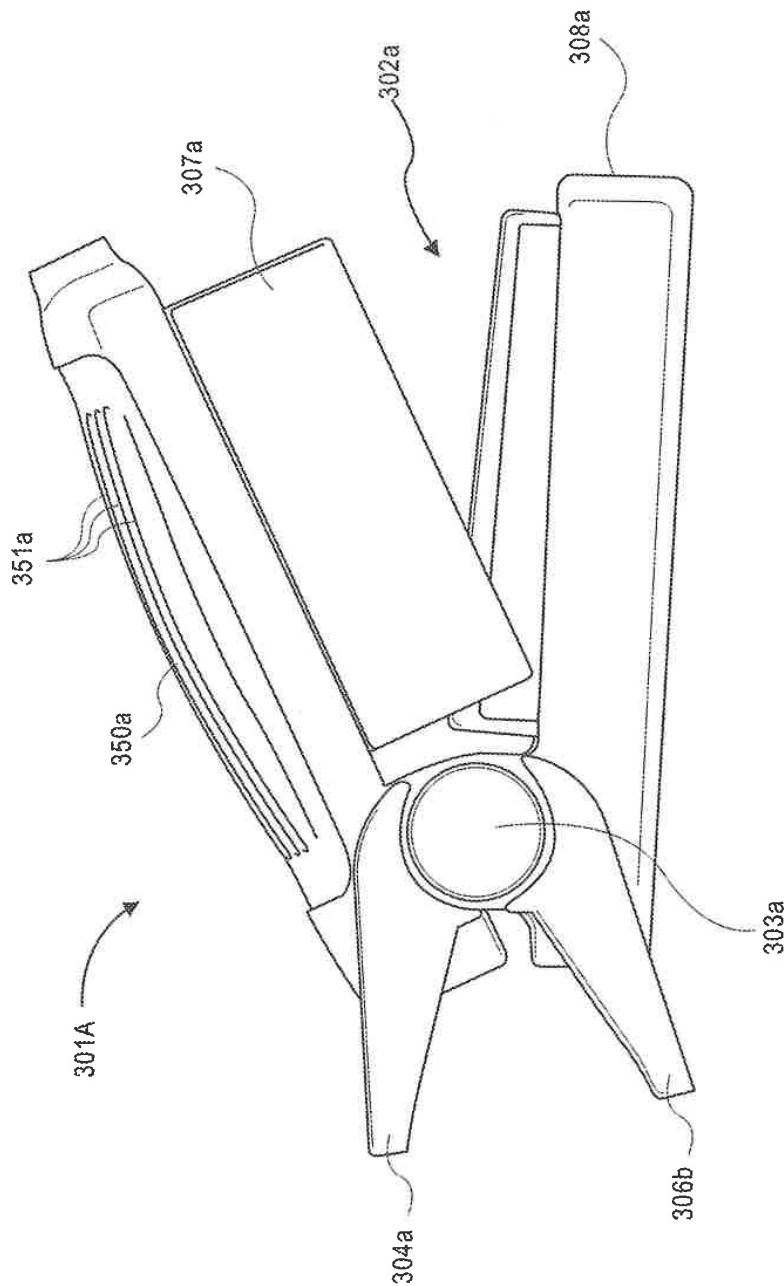


FIG. 3A

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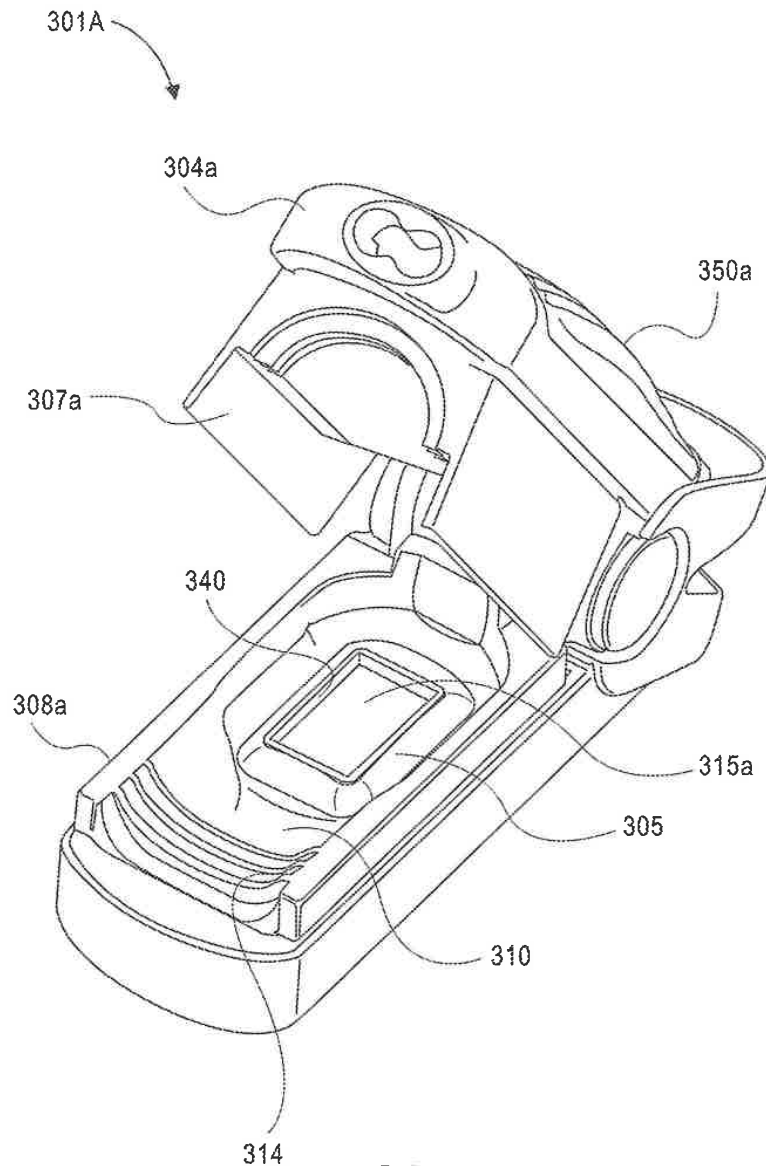


FIG. 3B

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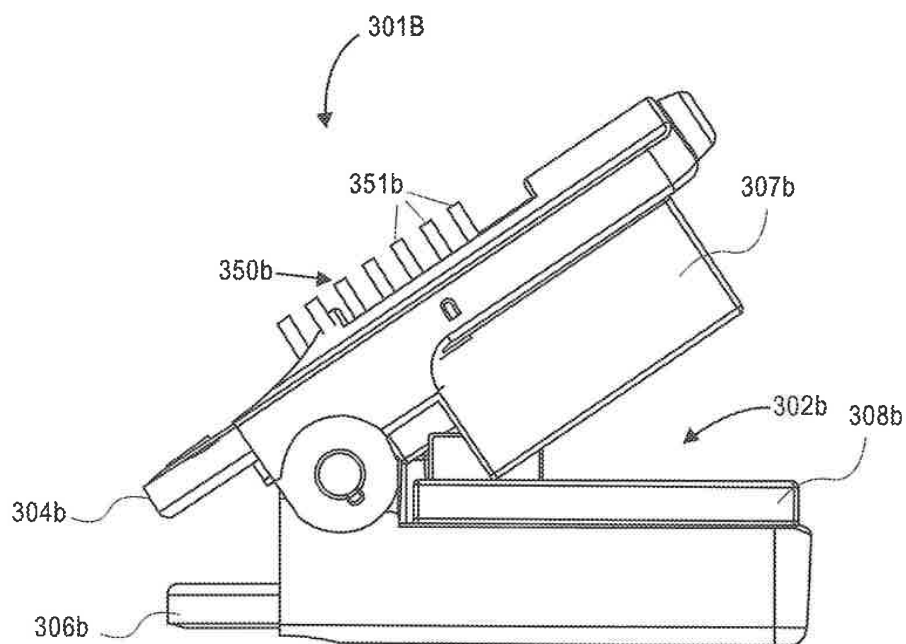


FIG. 3D

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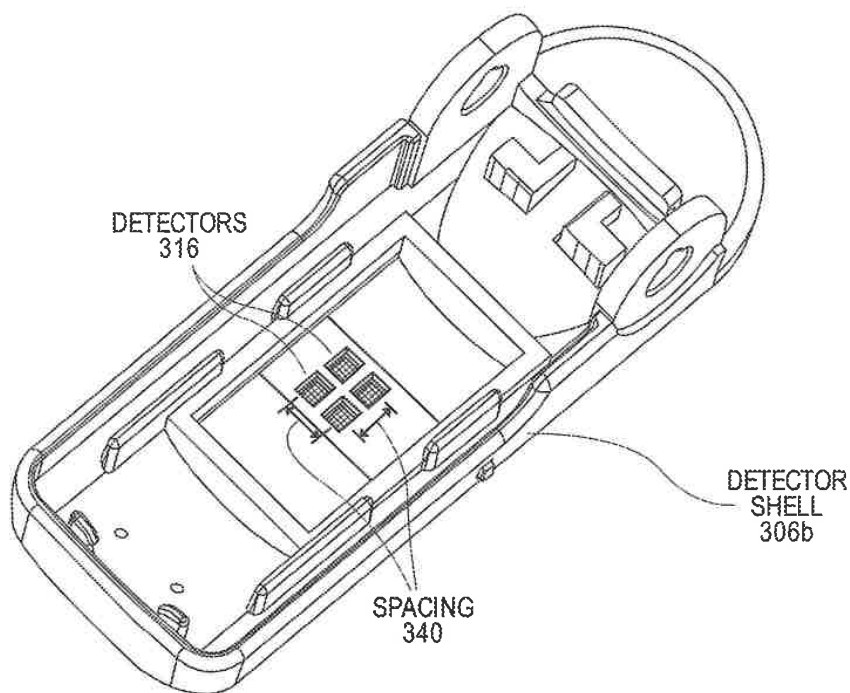


FIG. 3E

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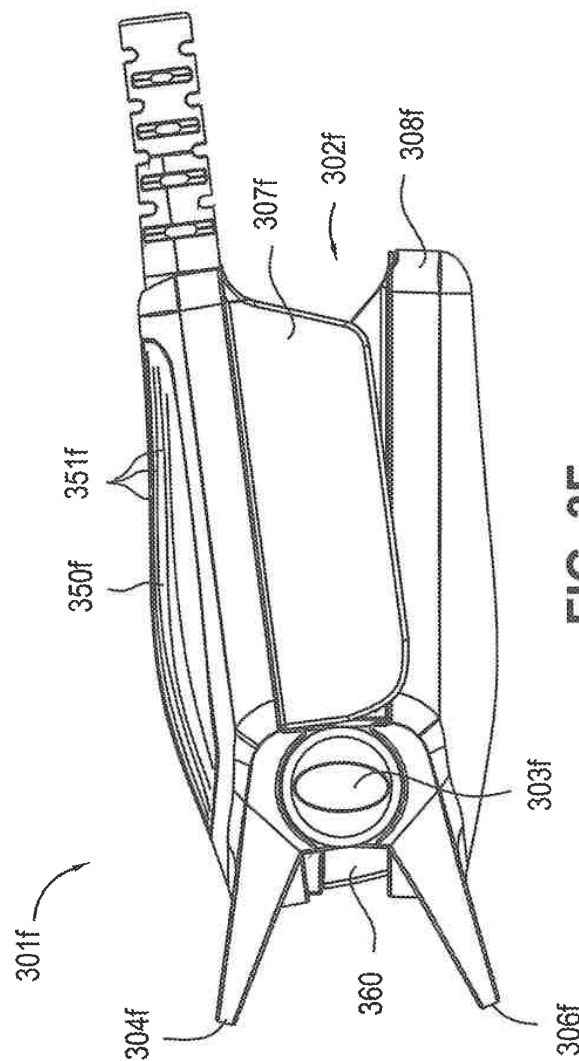


FIG. 3F

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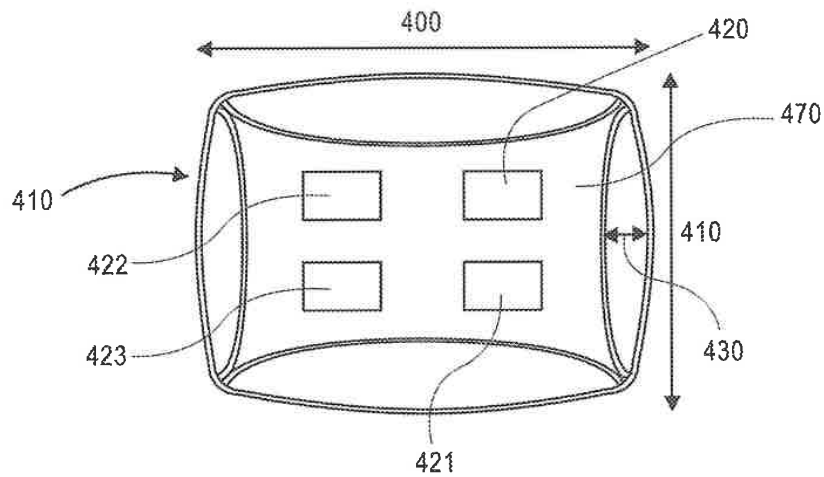


FIG. 4A

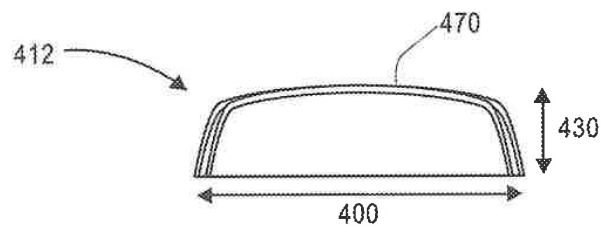


FIG. 4B

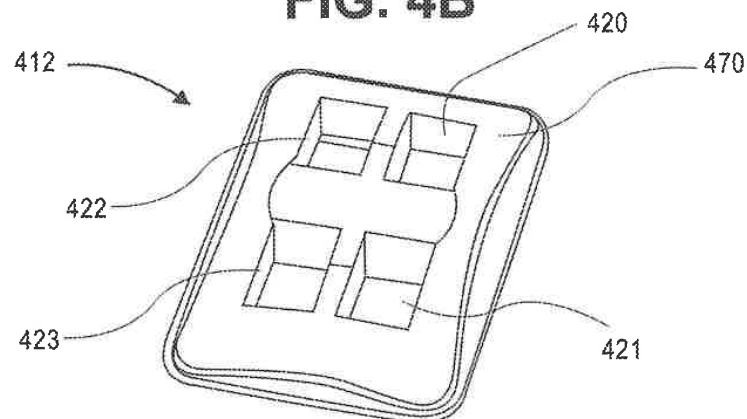


FIG. 4C

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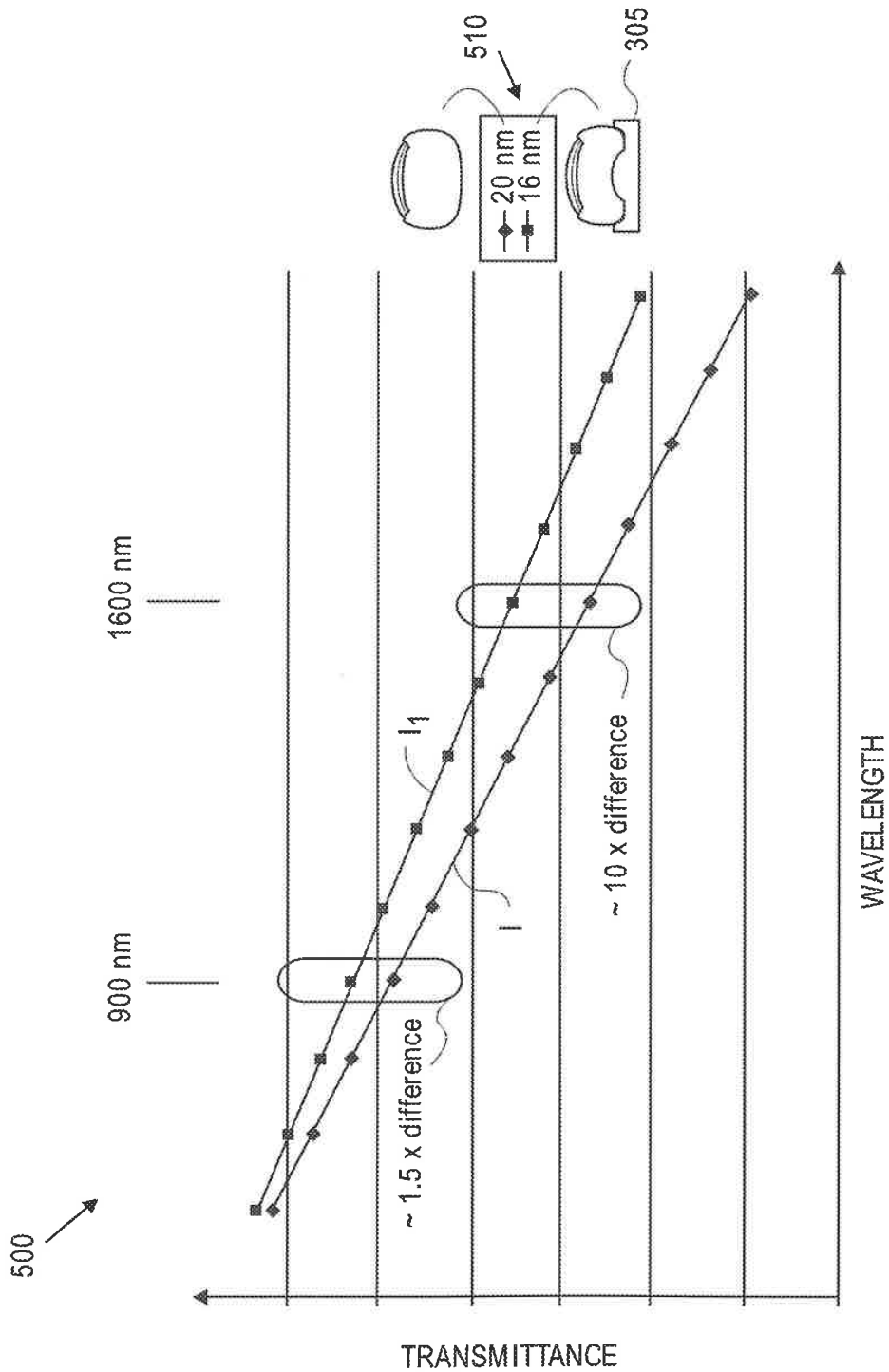


FIG. 5

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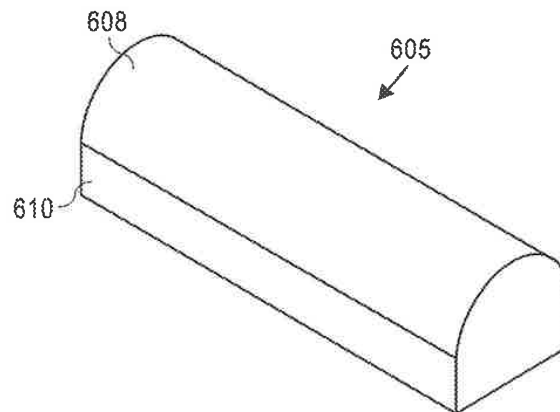


FIG. 6A

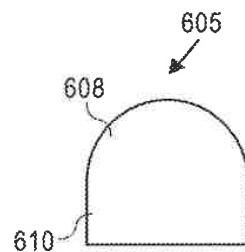


FIG. 6B

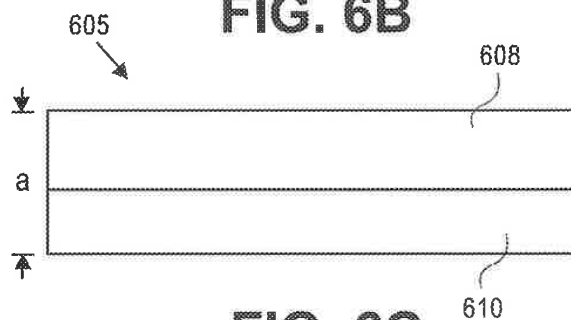


FIG. 6C



FIG. 6D

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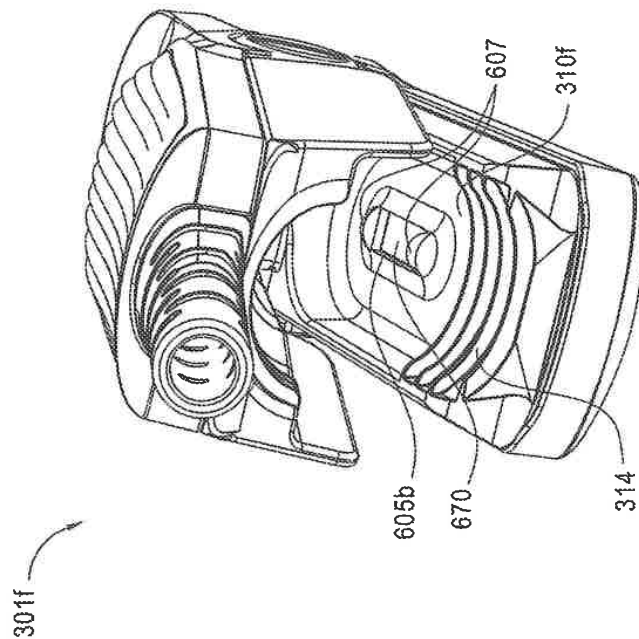


FIG. 6E

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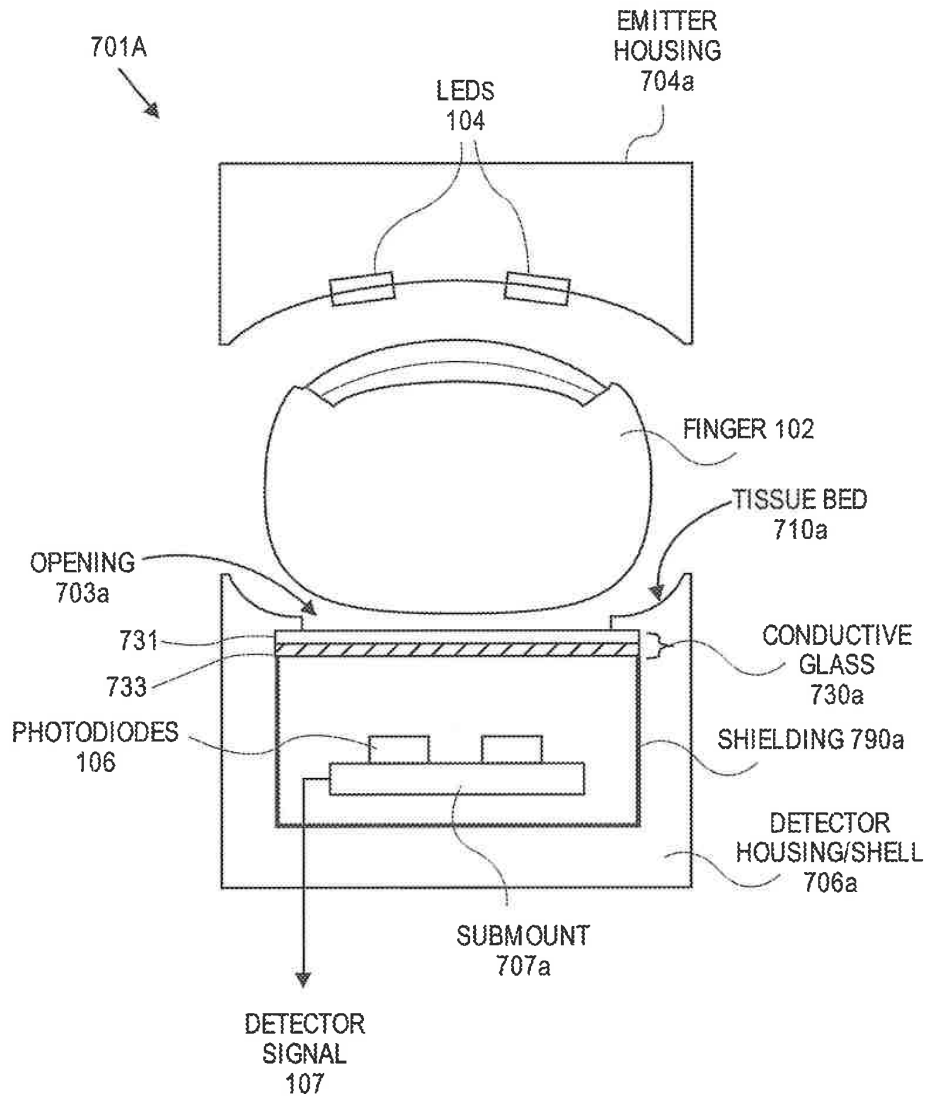


FIG. 7A

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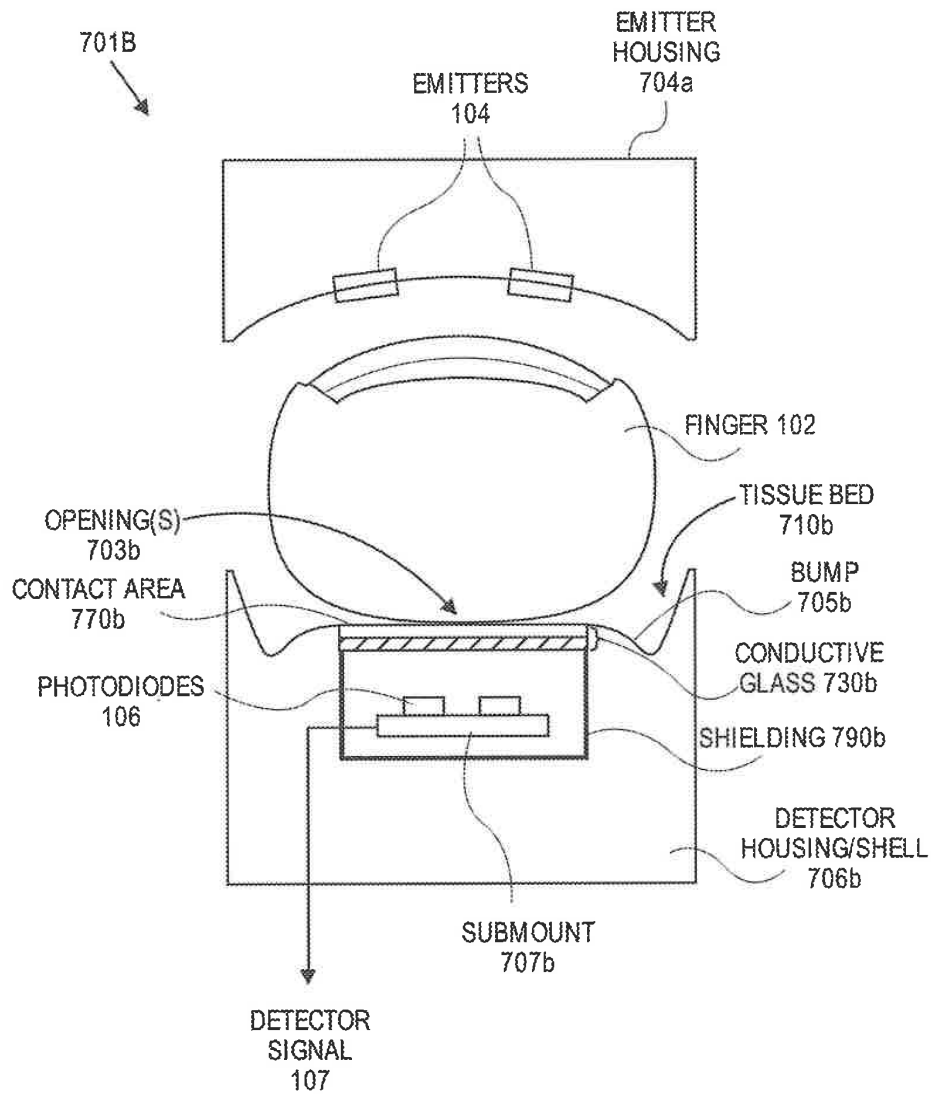


FIG. 7B

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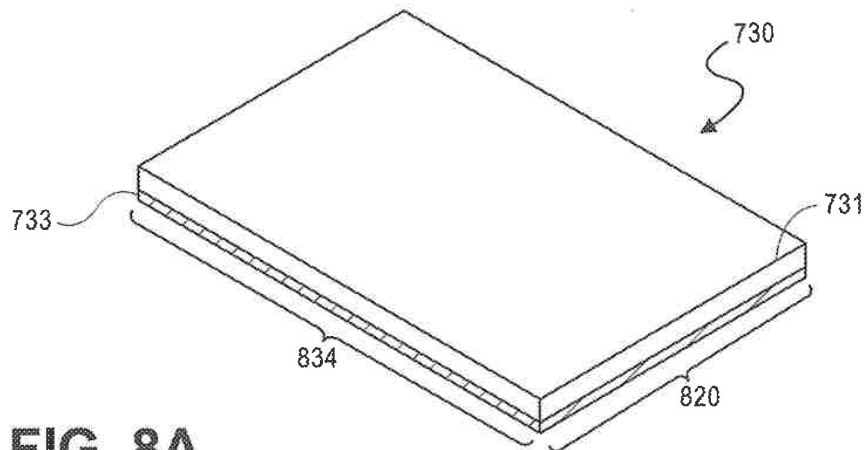


FIG. 8A

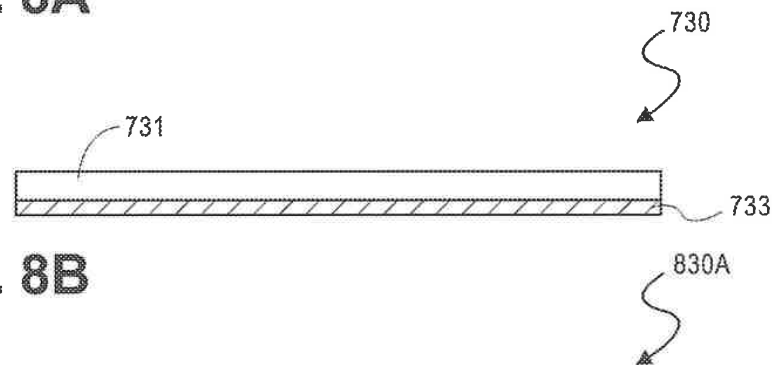


FIG. 8B

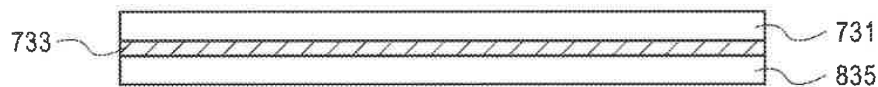


FIG. 8C

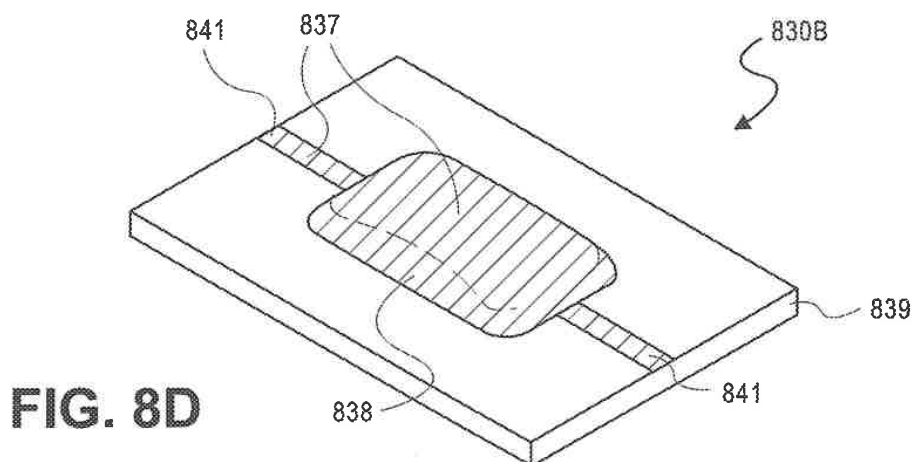


FIG. 8D

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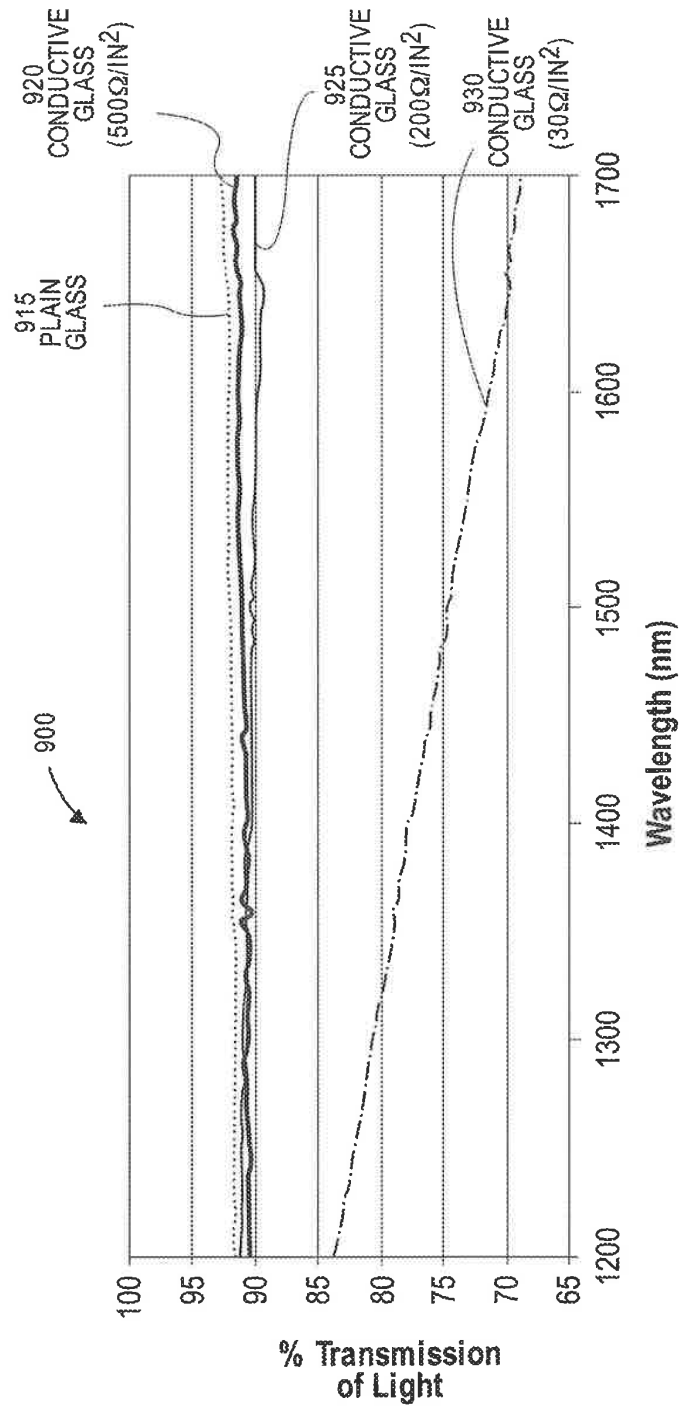


FIG. 9

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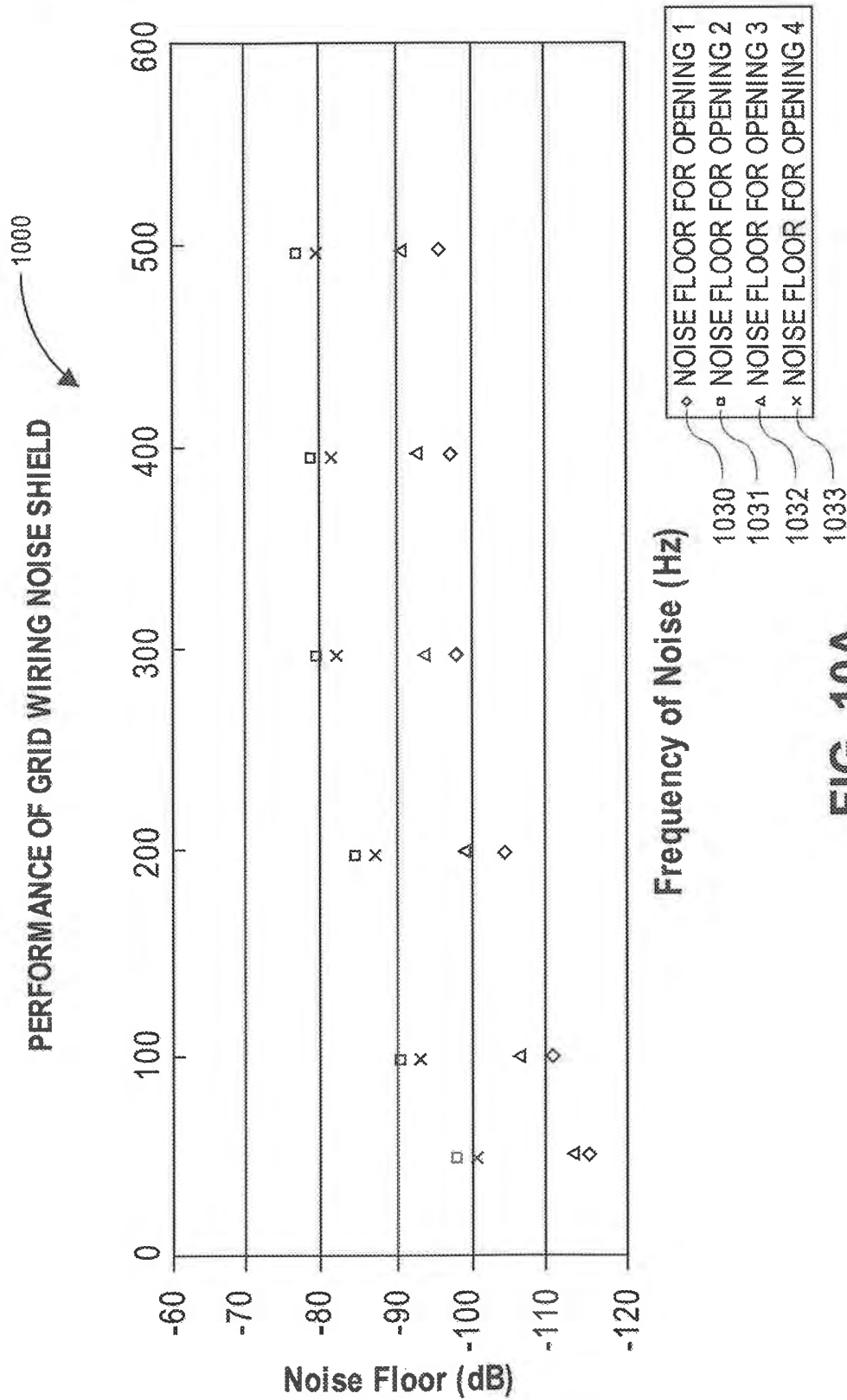


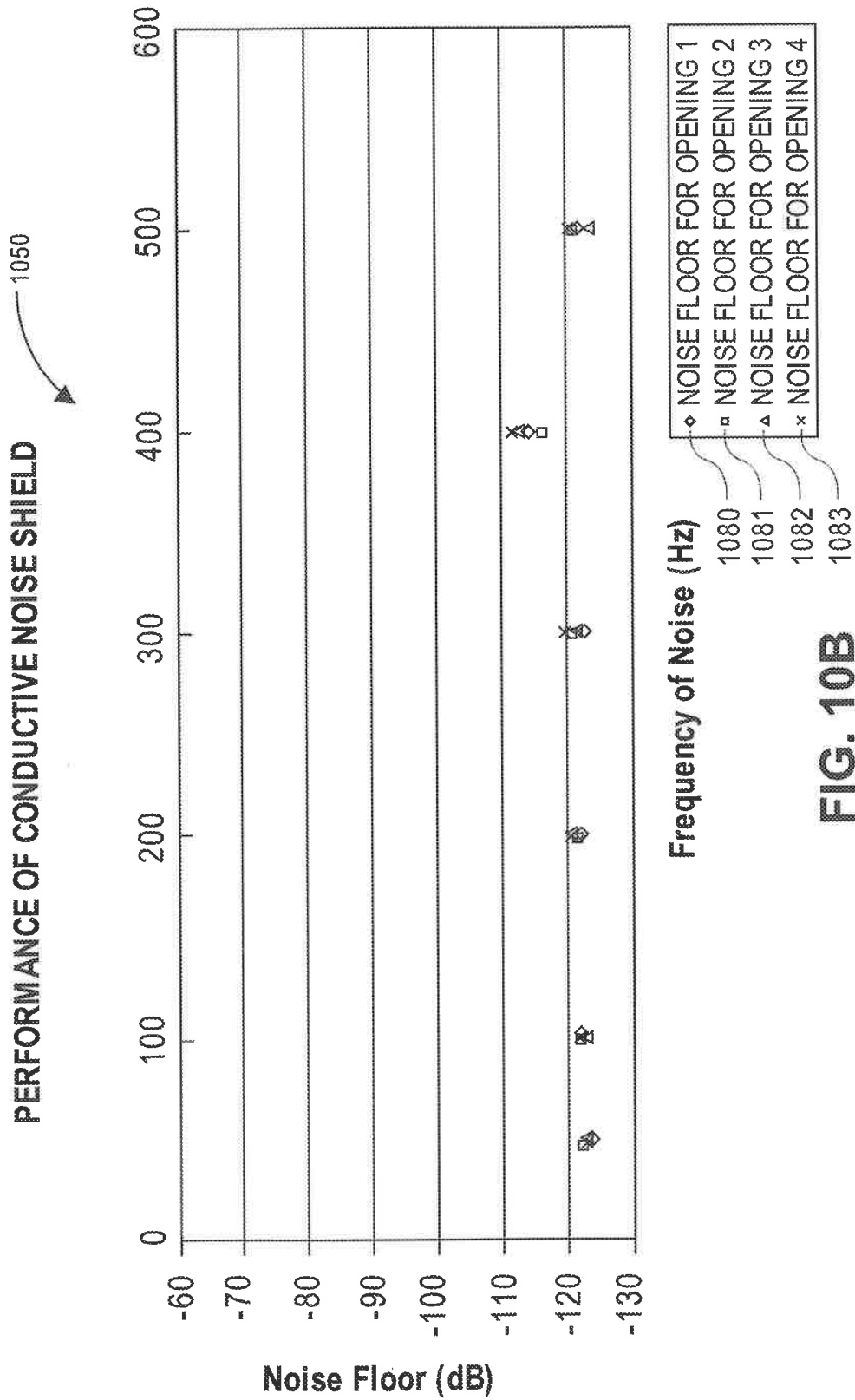
FIG. 10A

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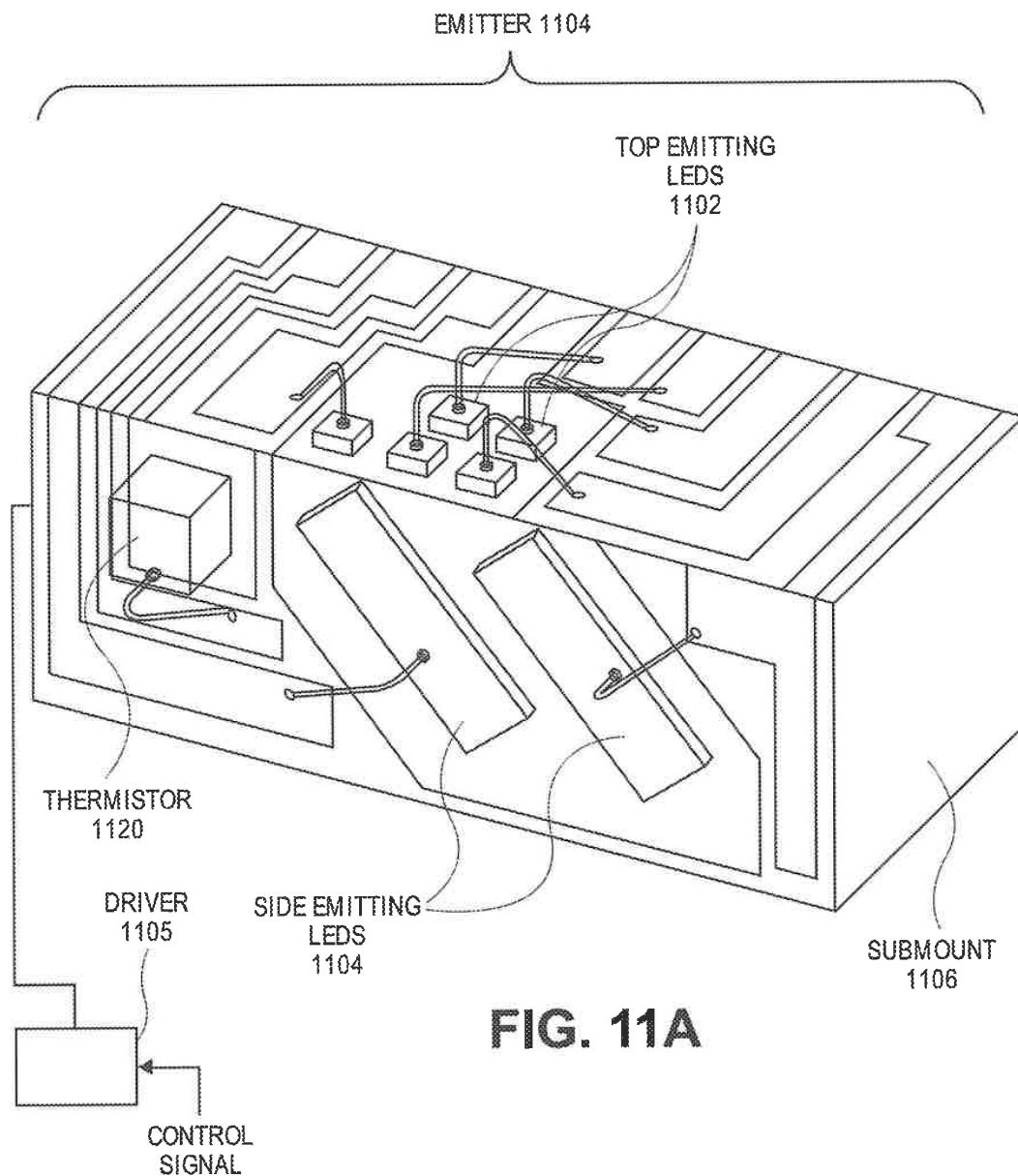


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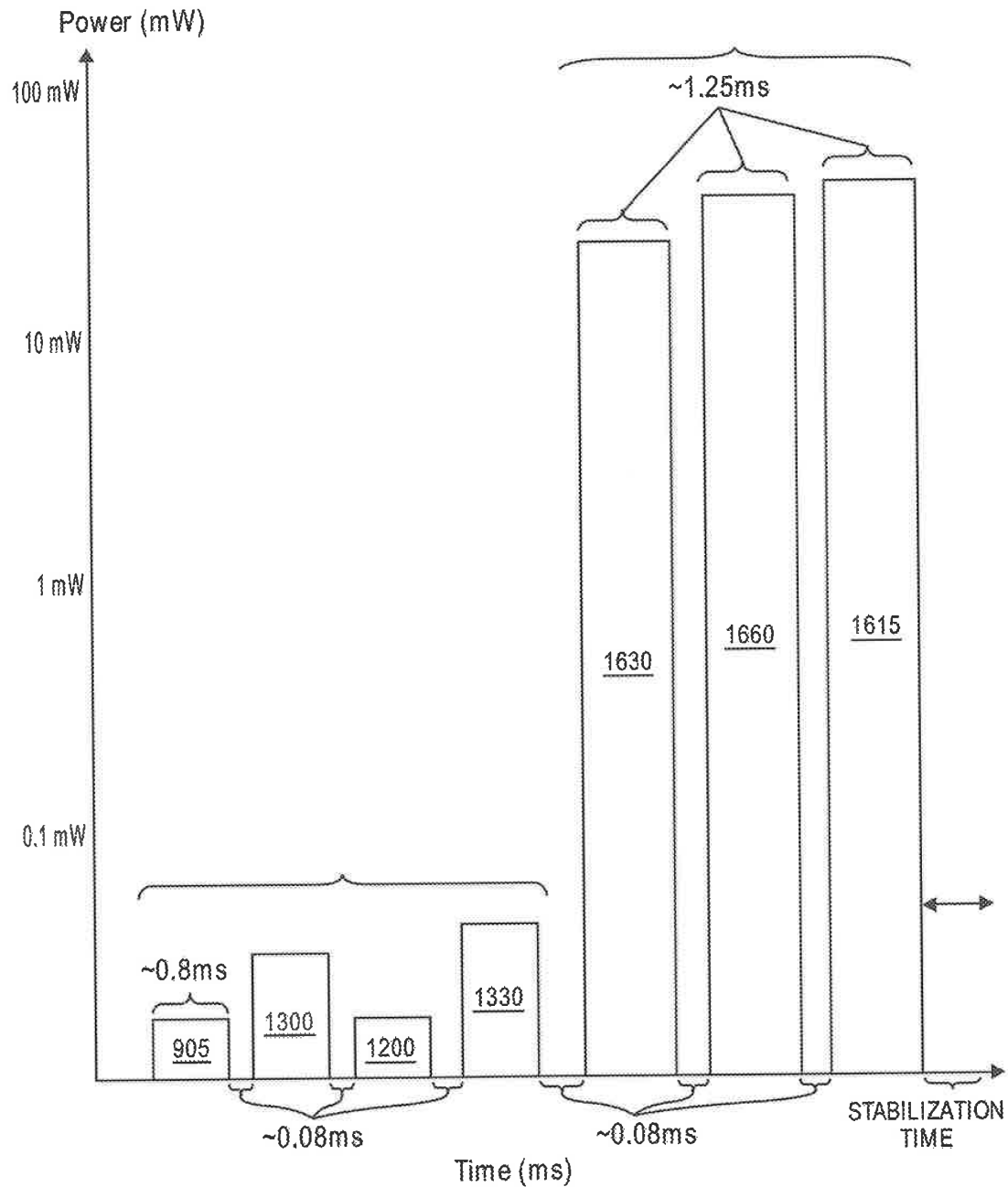


FIG. 11B

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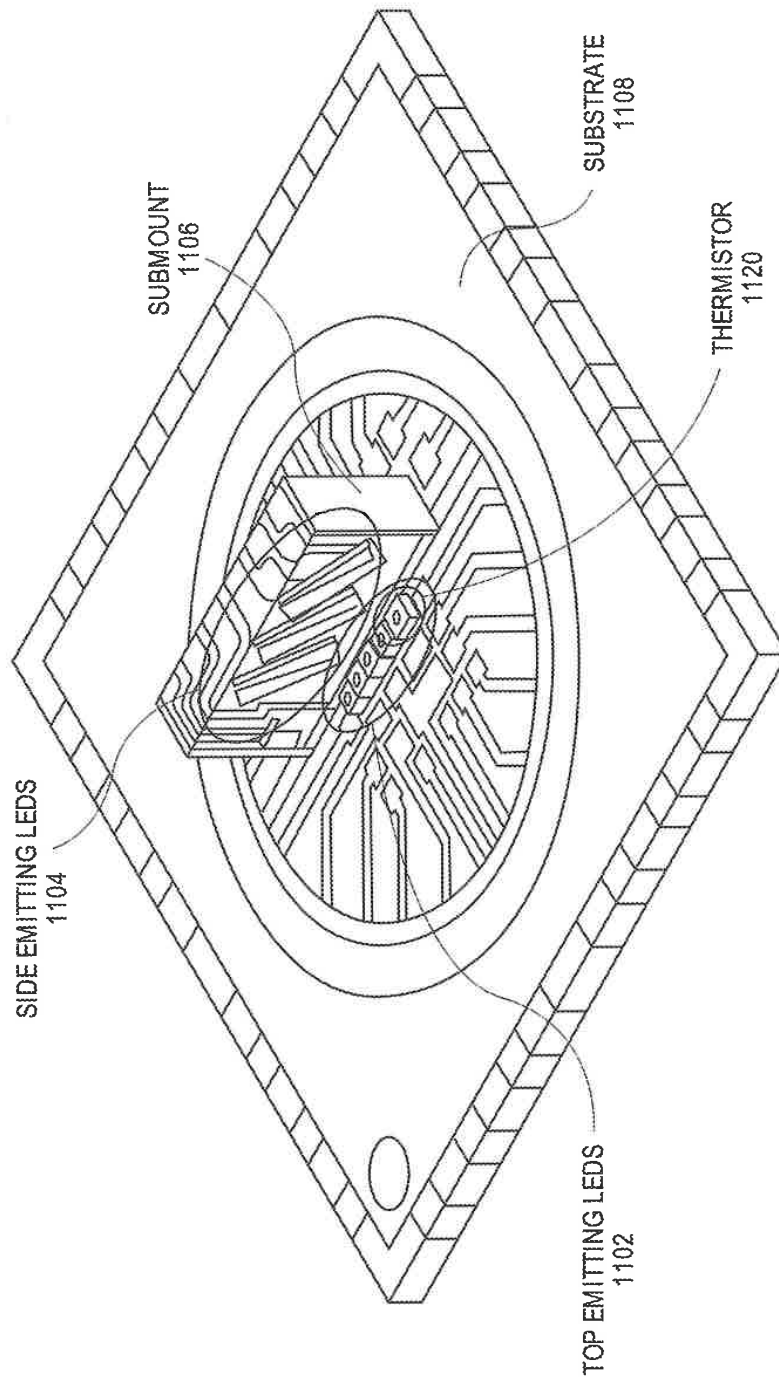


FIG. 11C

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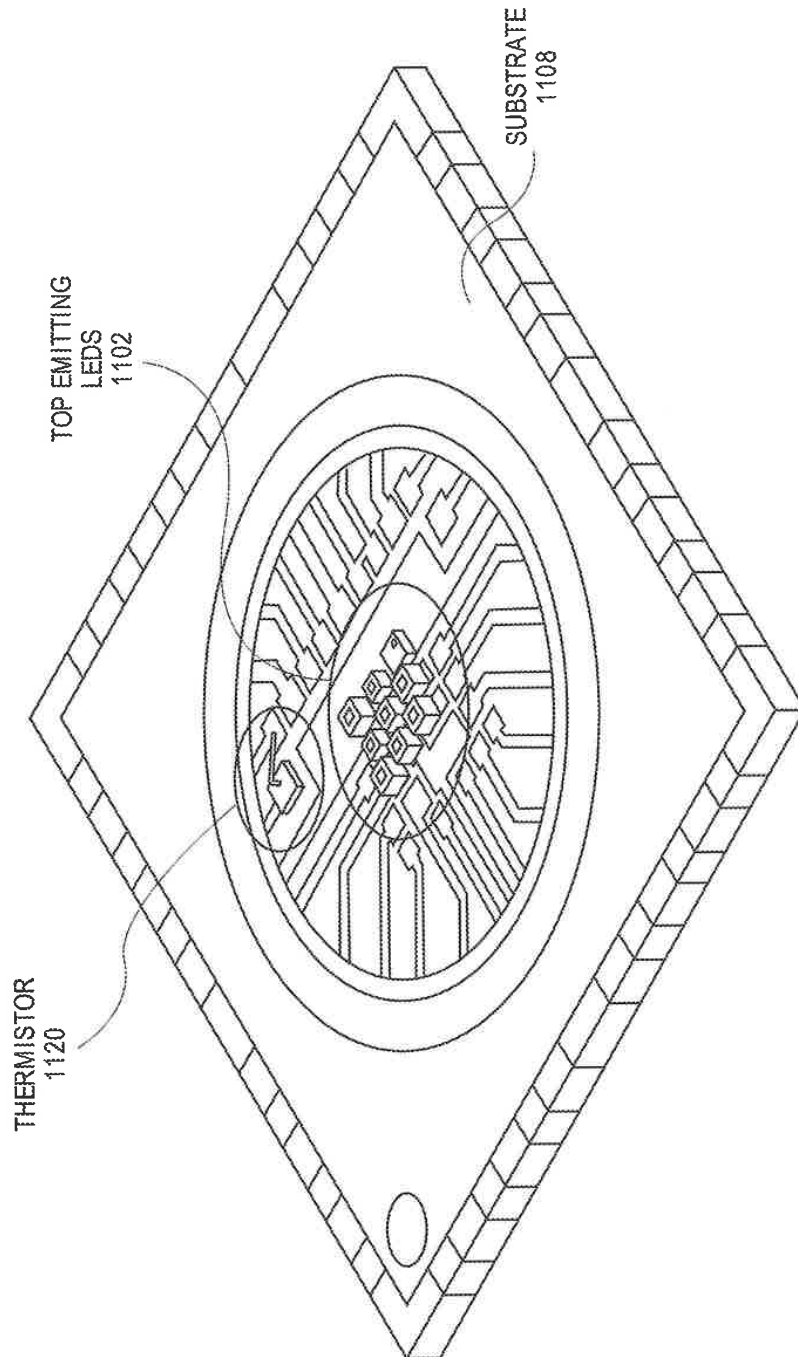


FIG. 11D

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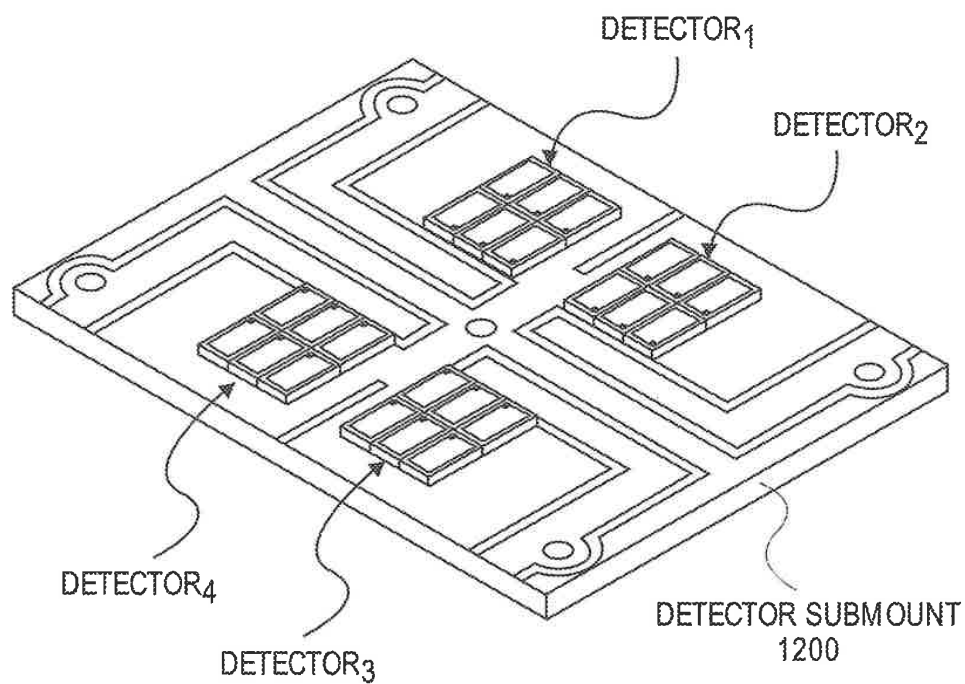


FIG. 12A

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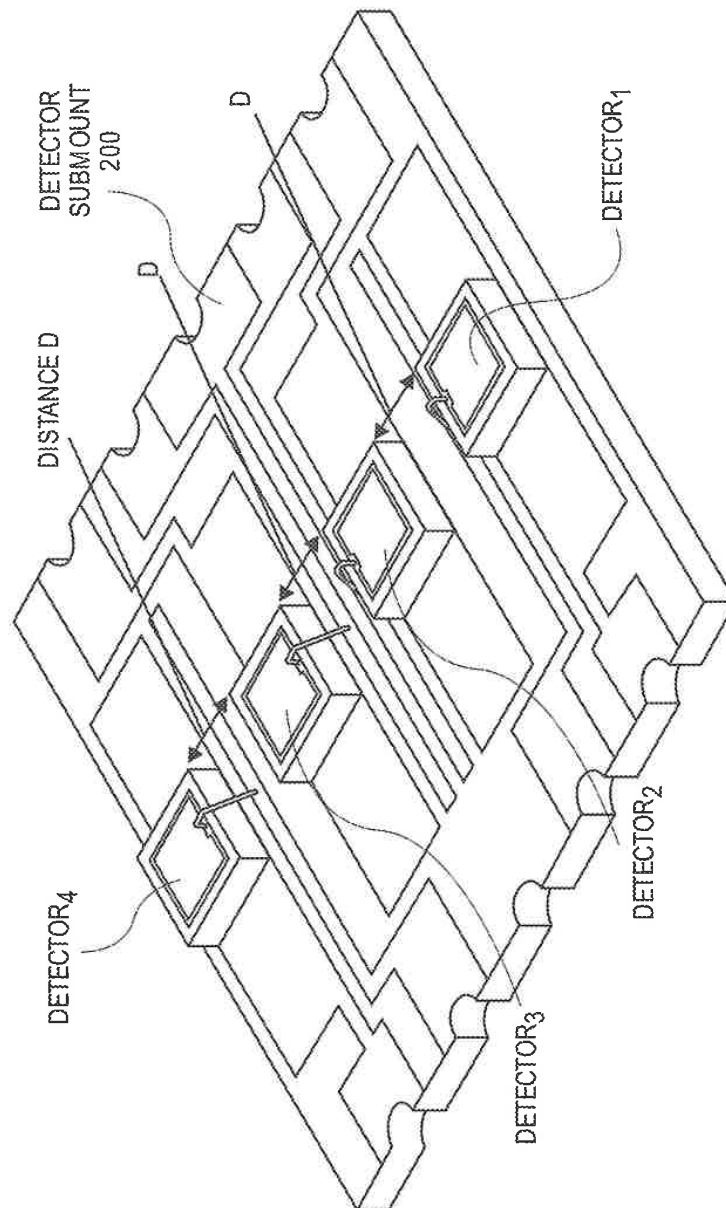


FIG. 12B

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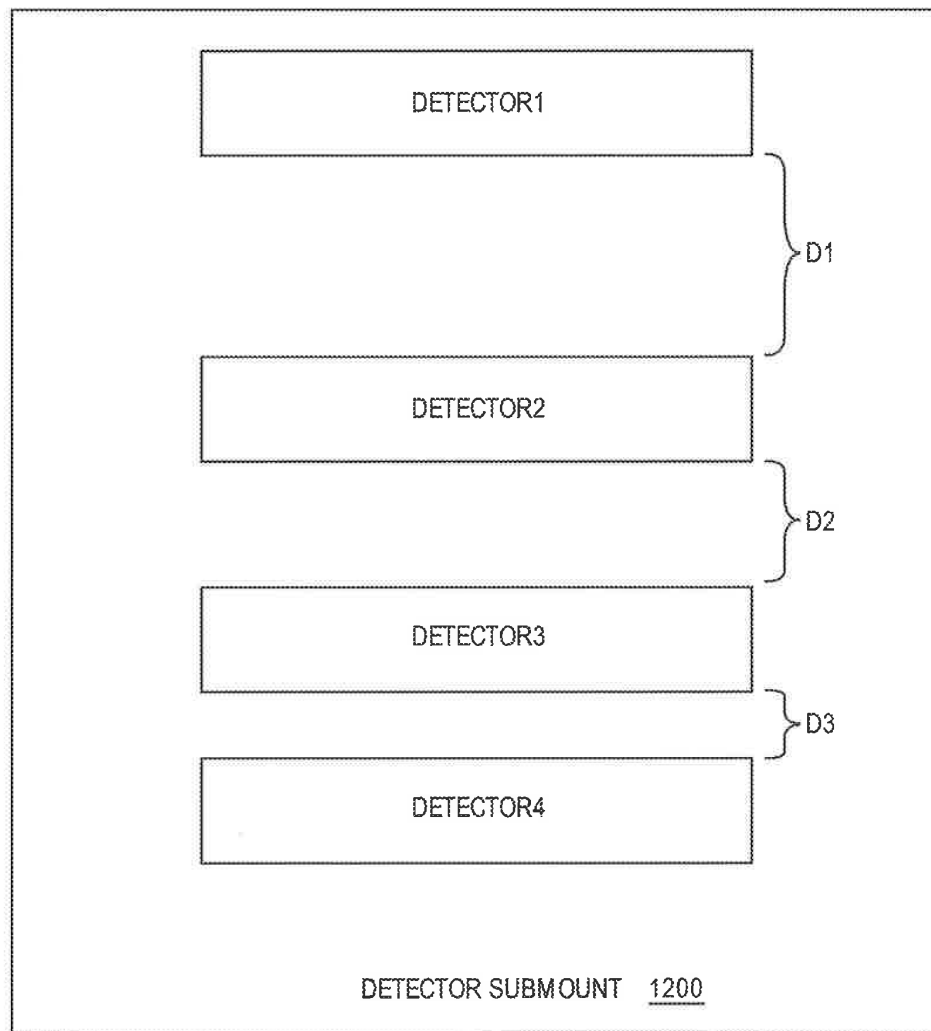


FIG. 12C

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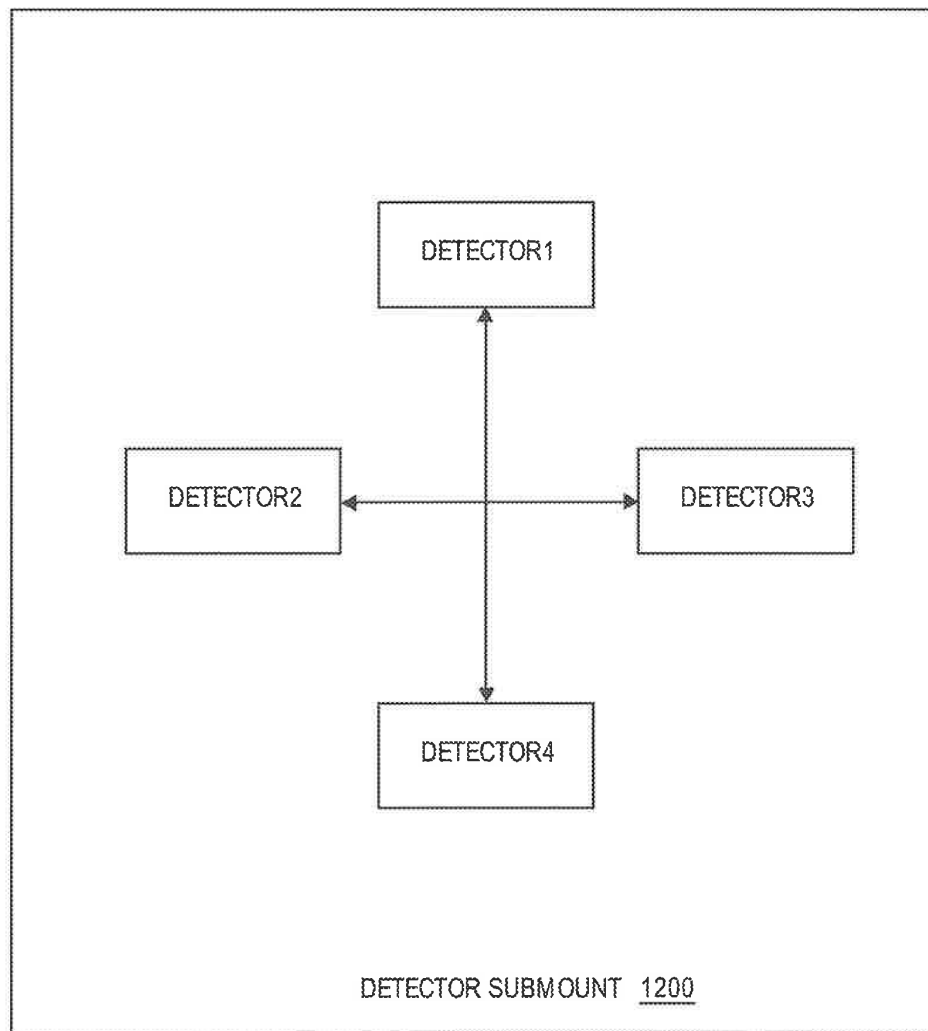


FIG. 12D

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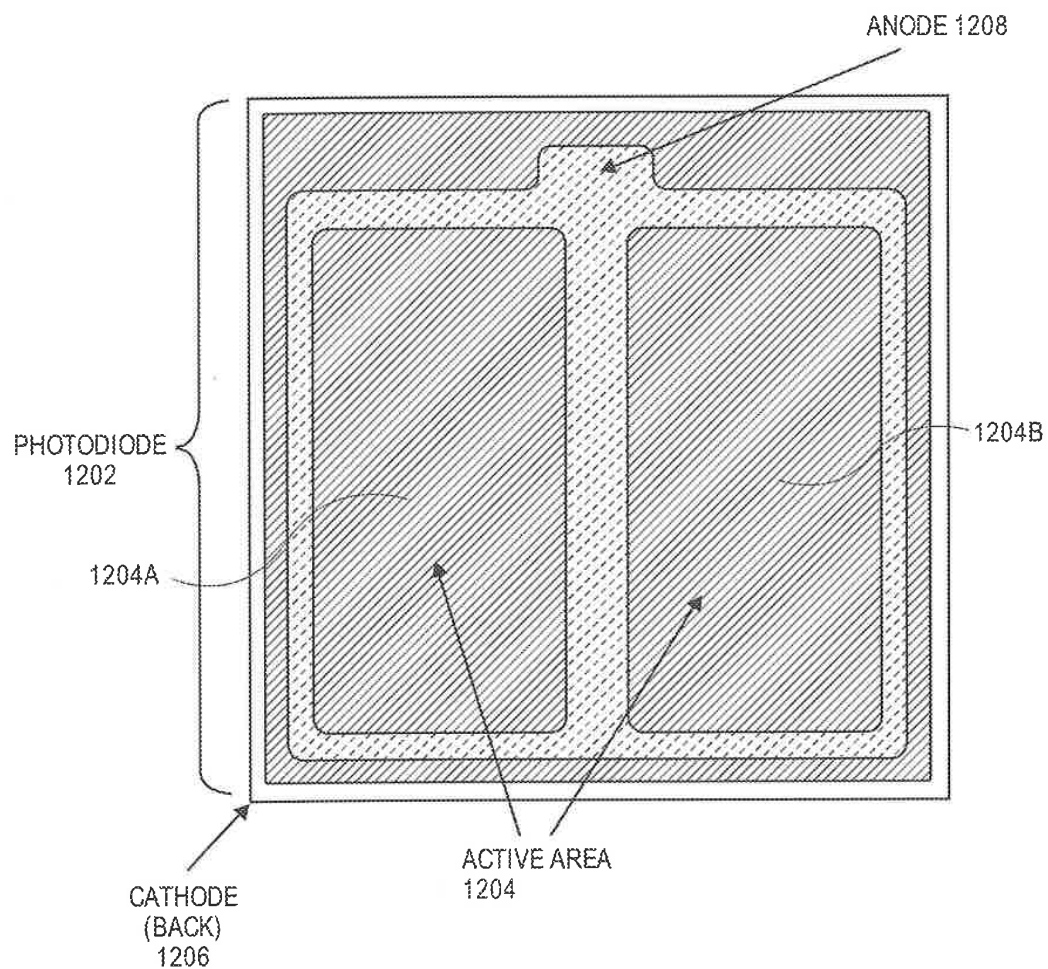


FIG. 12E

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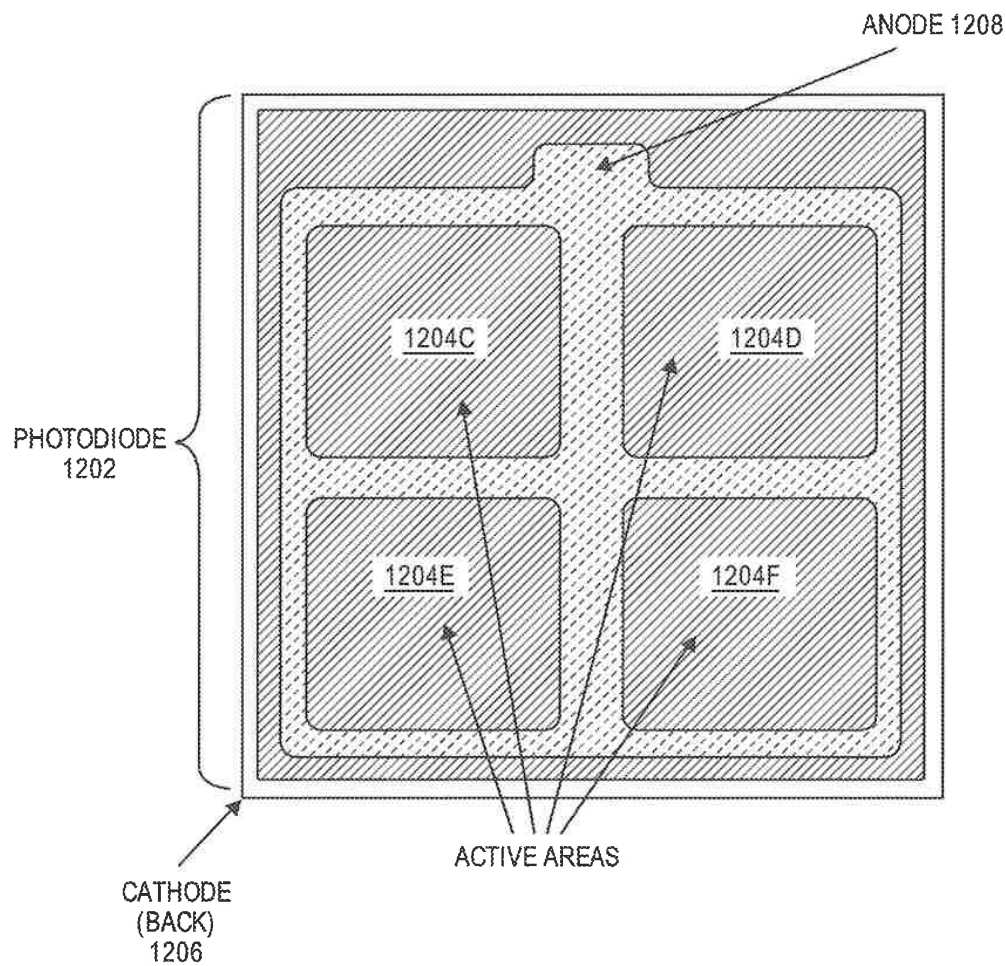


FIG. 12F

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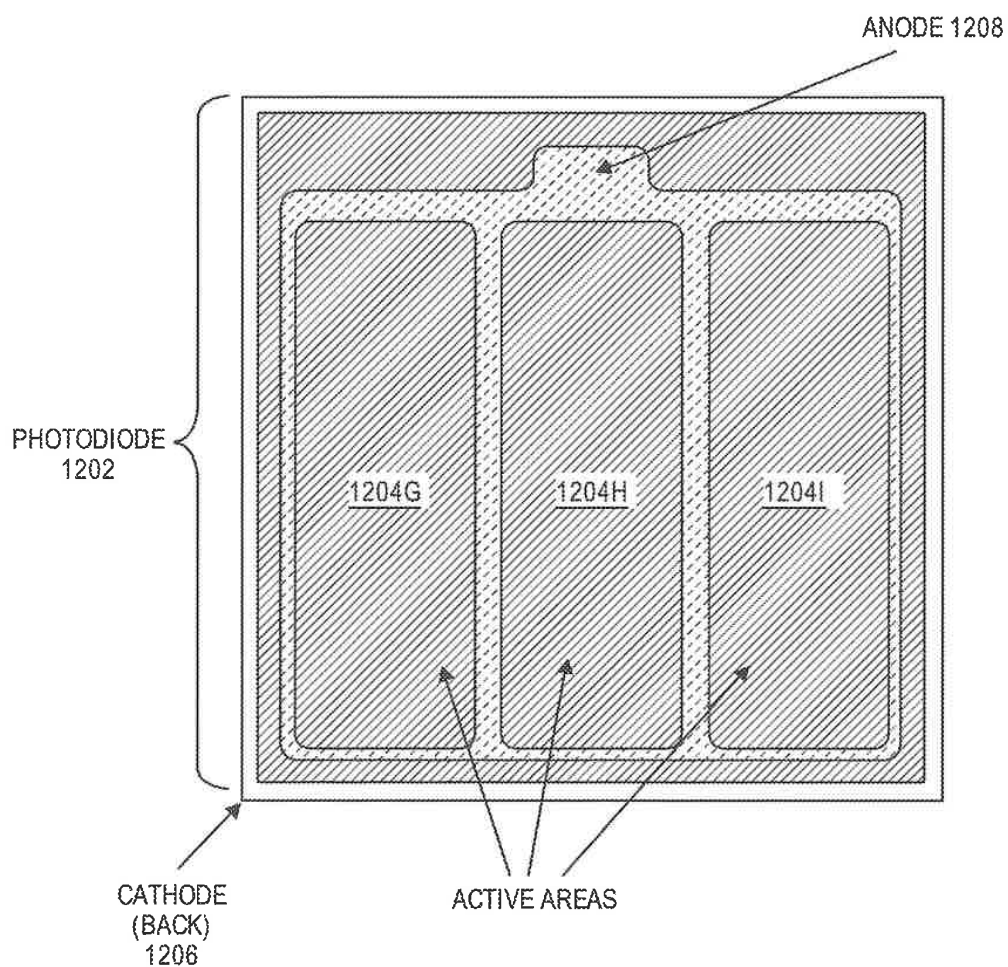


FIG. 12G

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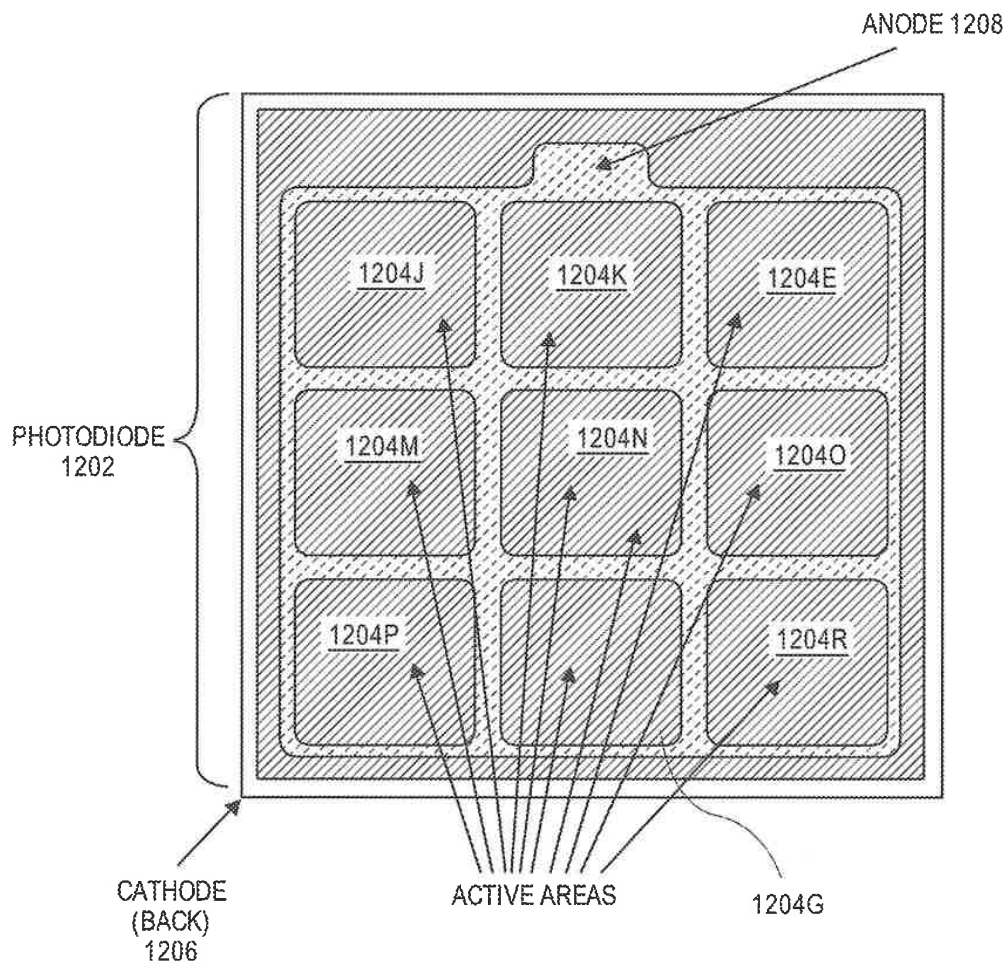


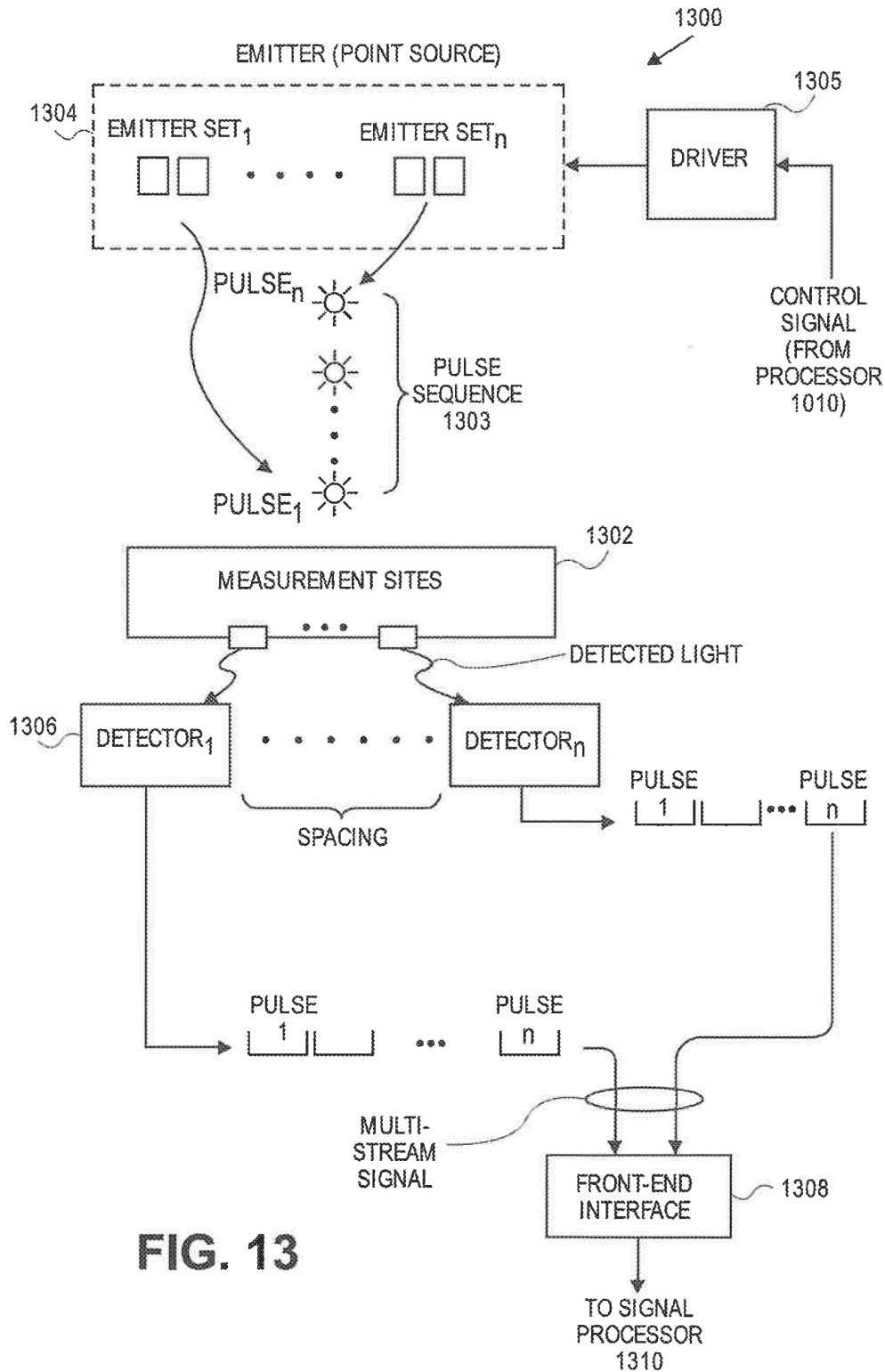
FIG. 12H

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**FIG. 13**

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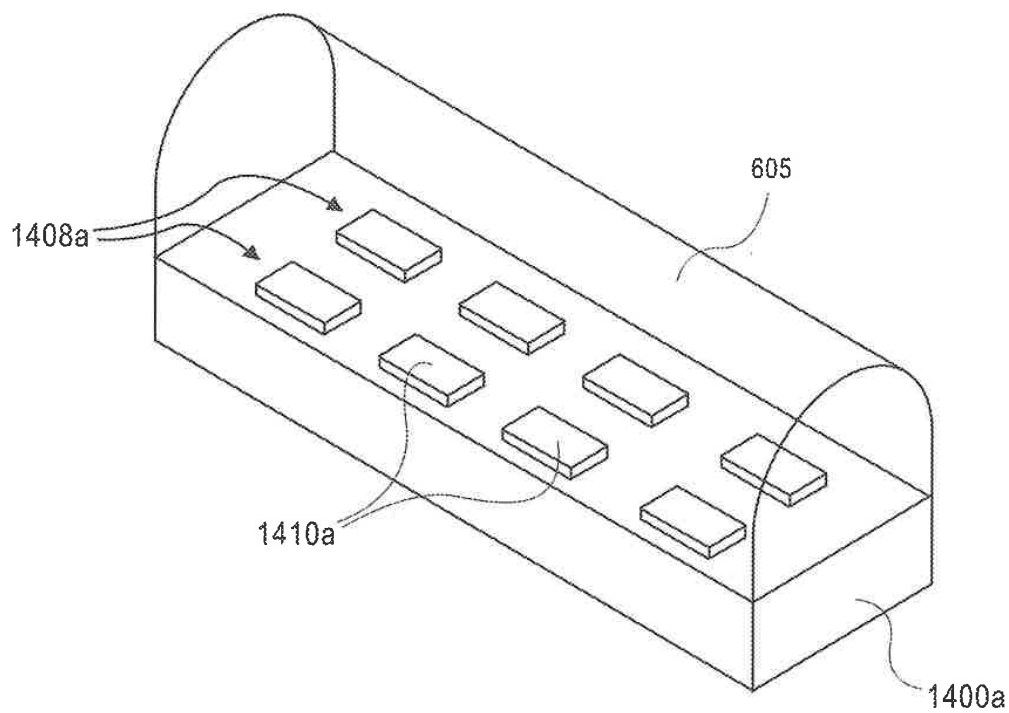


FIG. 14A

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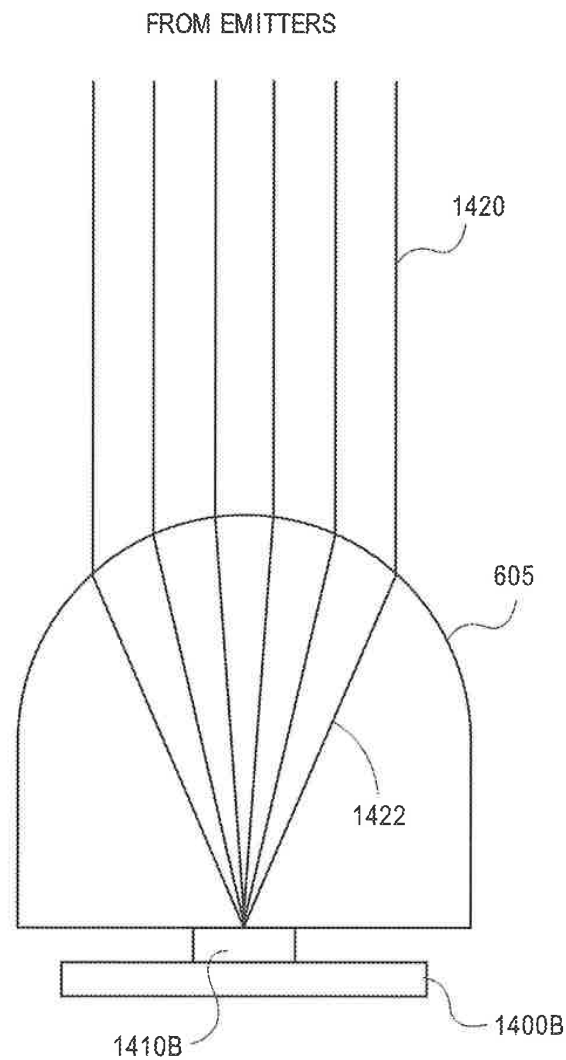


FIG. 14B

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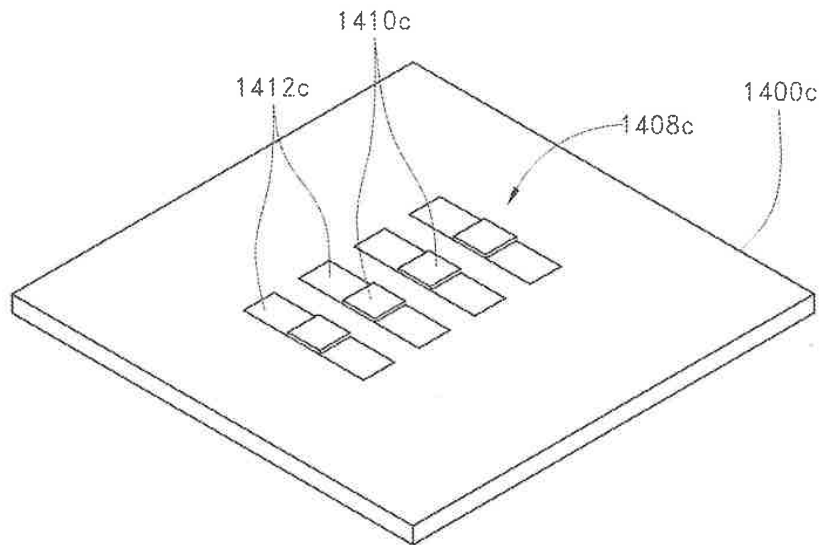


FIG. 14C

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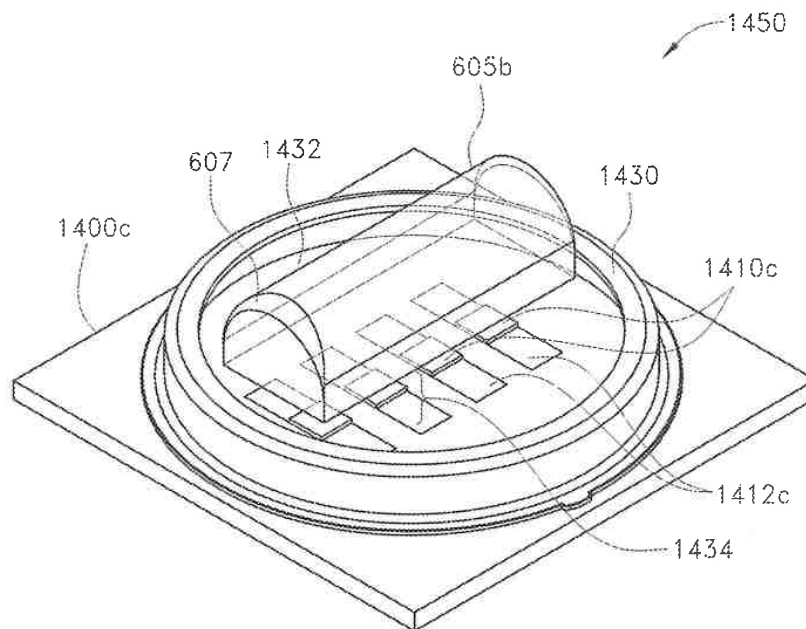


FIG. 14D

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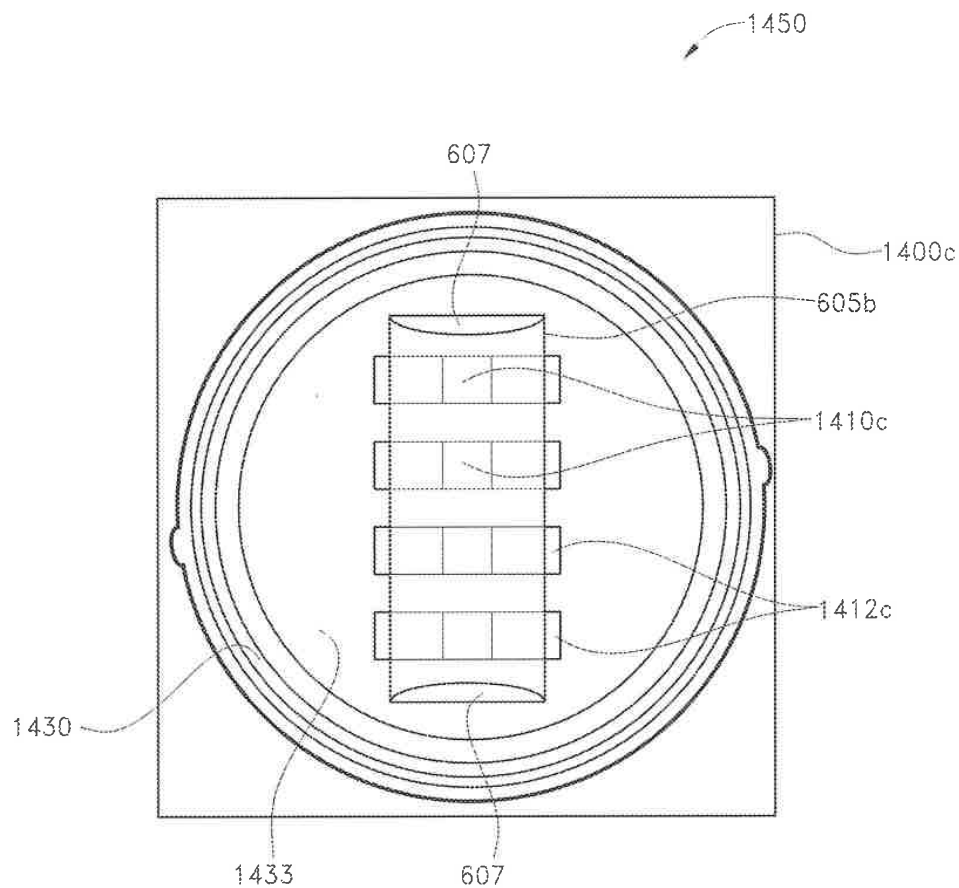


FIG. 14E

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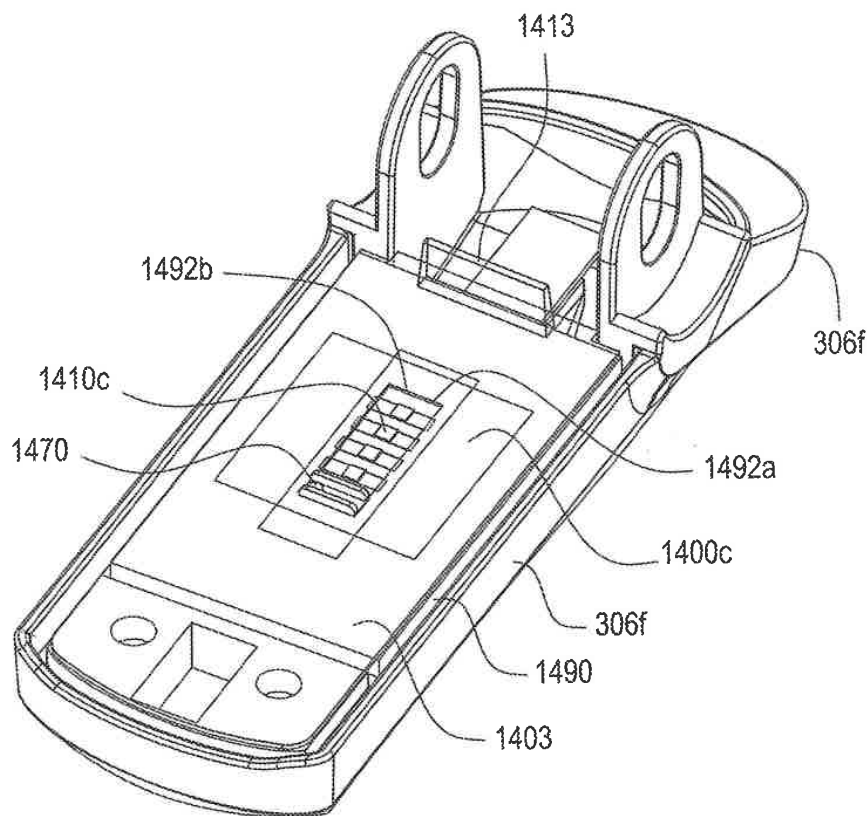


FIG. 14F

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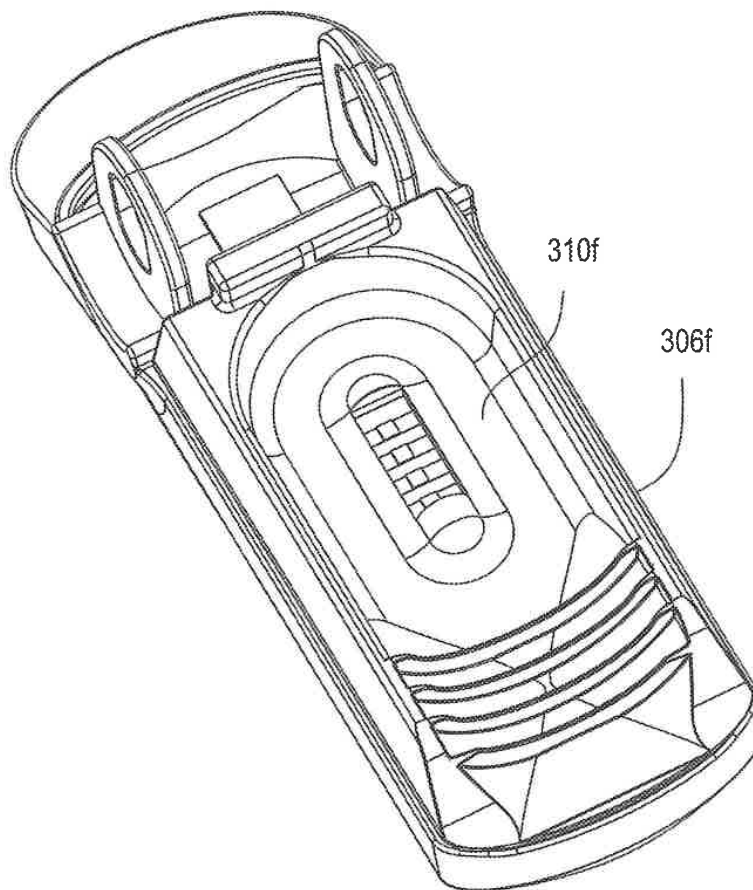


FIG. 14G

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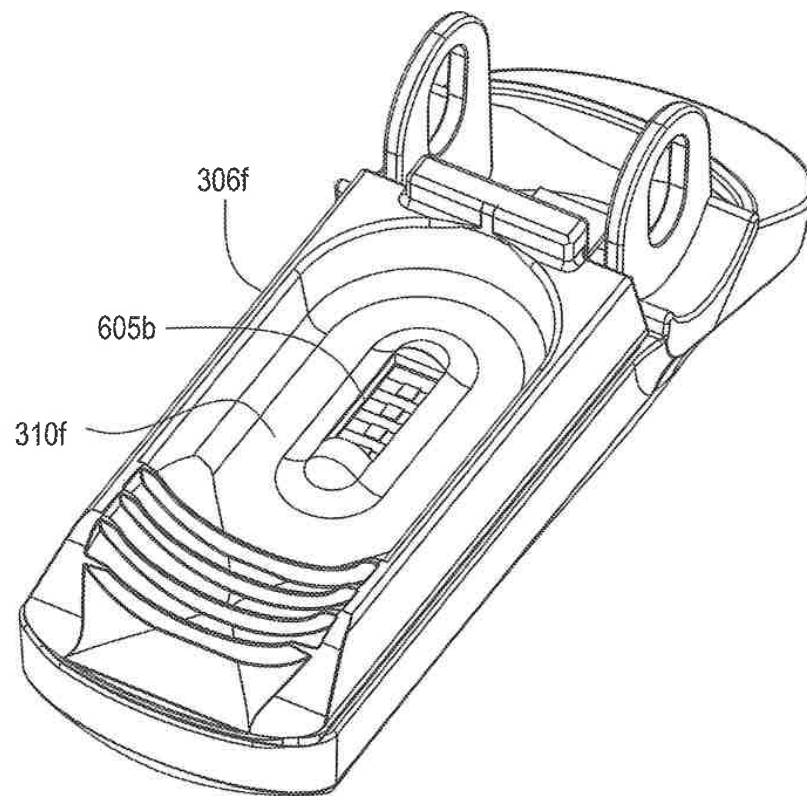


FIG. 14H

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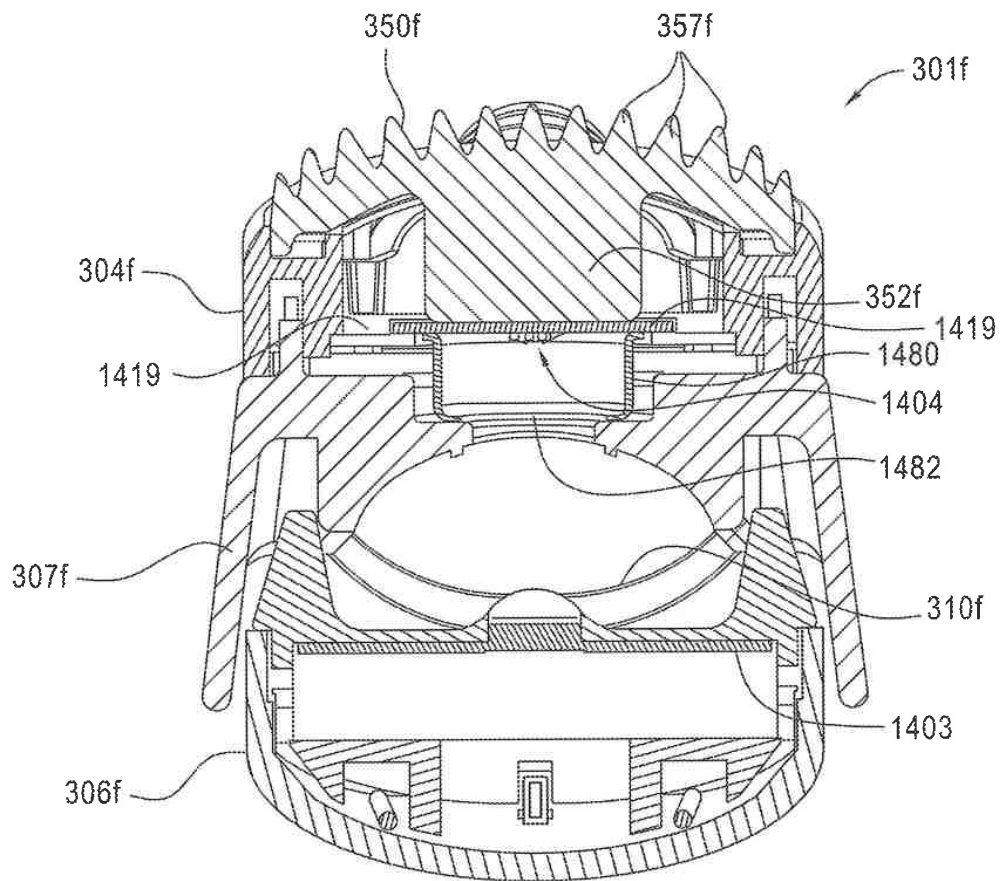


FIG. 14I

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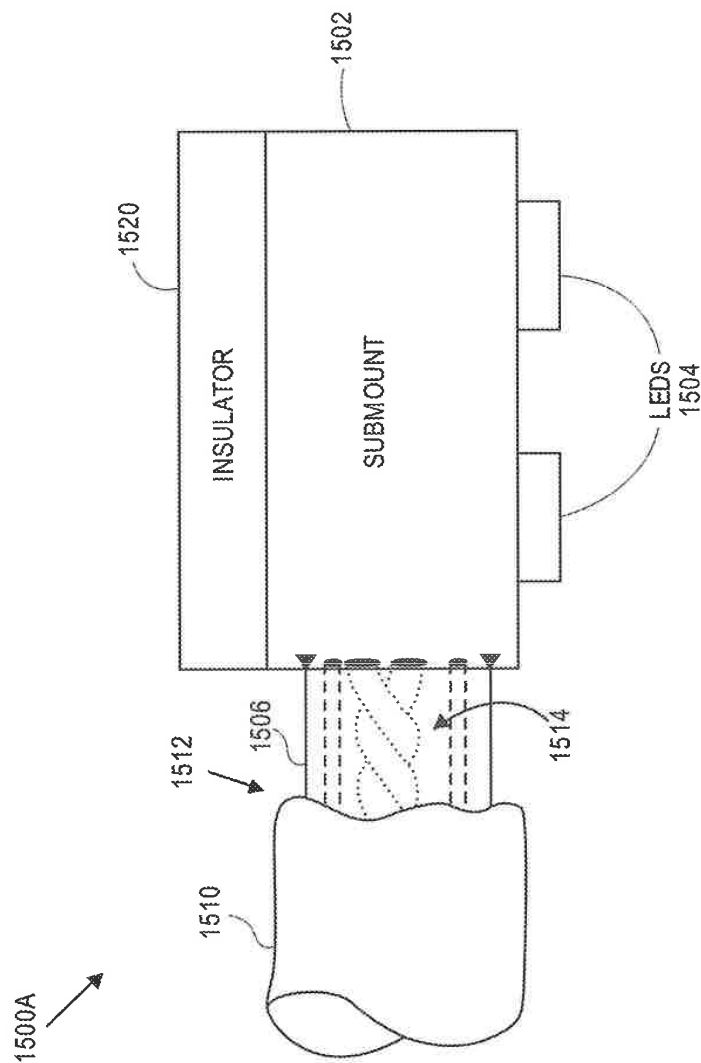


FIG. 15A

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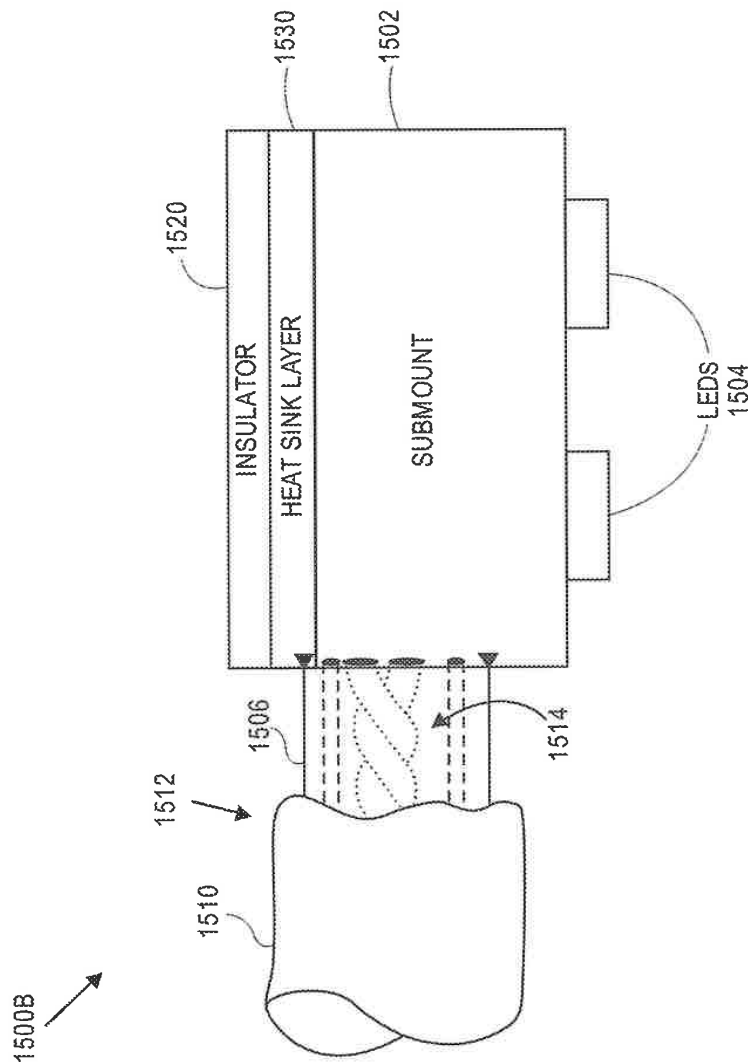


FIG. 15B

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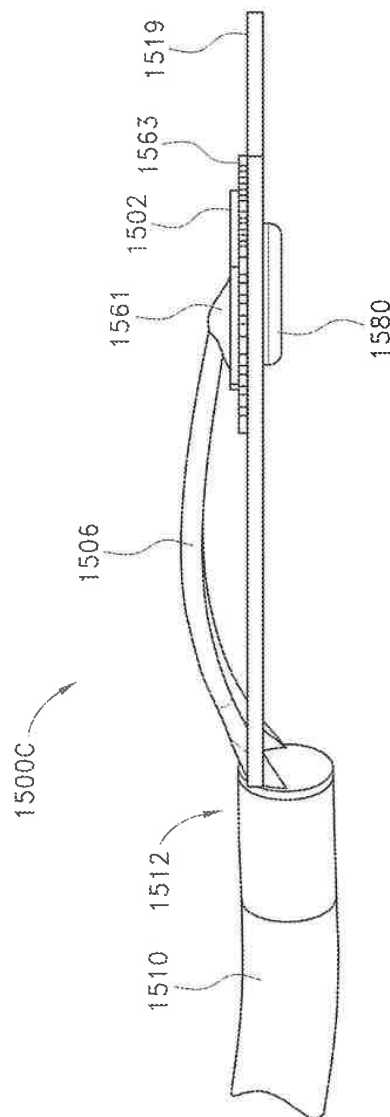


FIG. 15C

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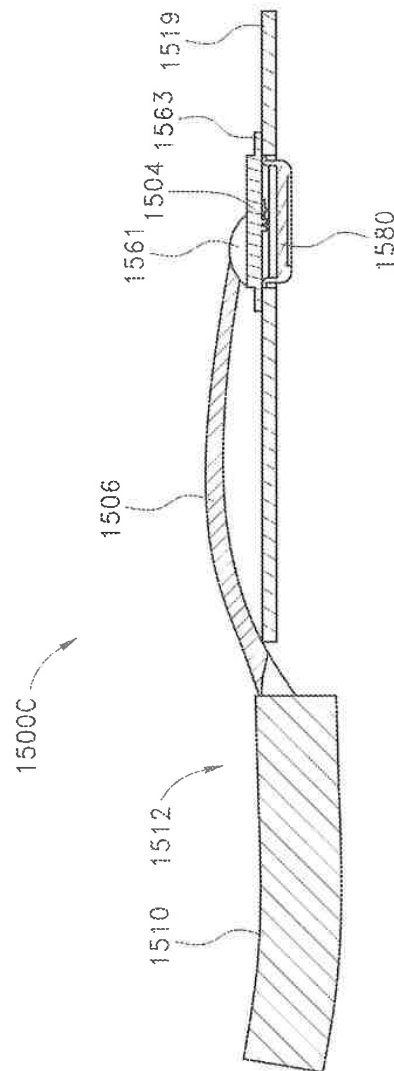


FIG. 15D

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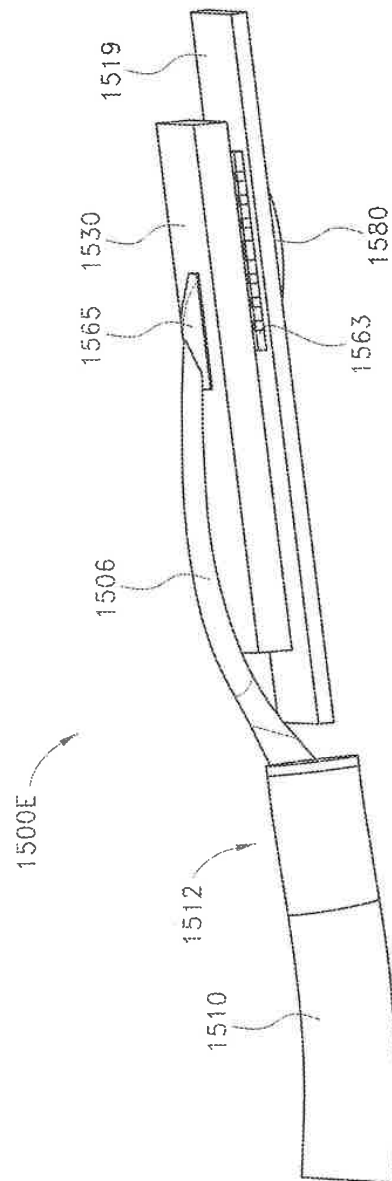


FIG. 15E

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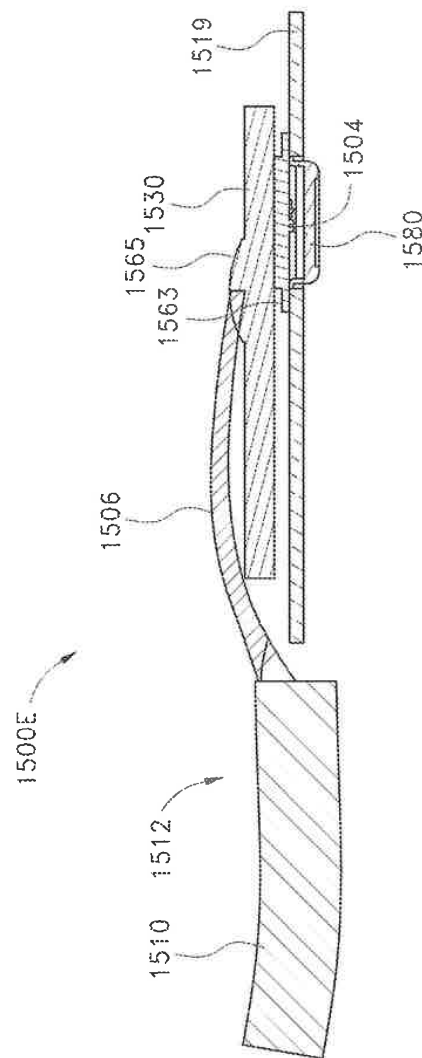


FIG. 15F

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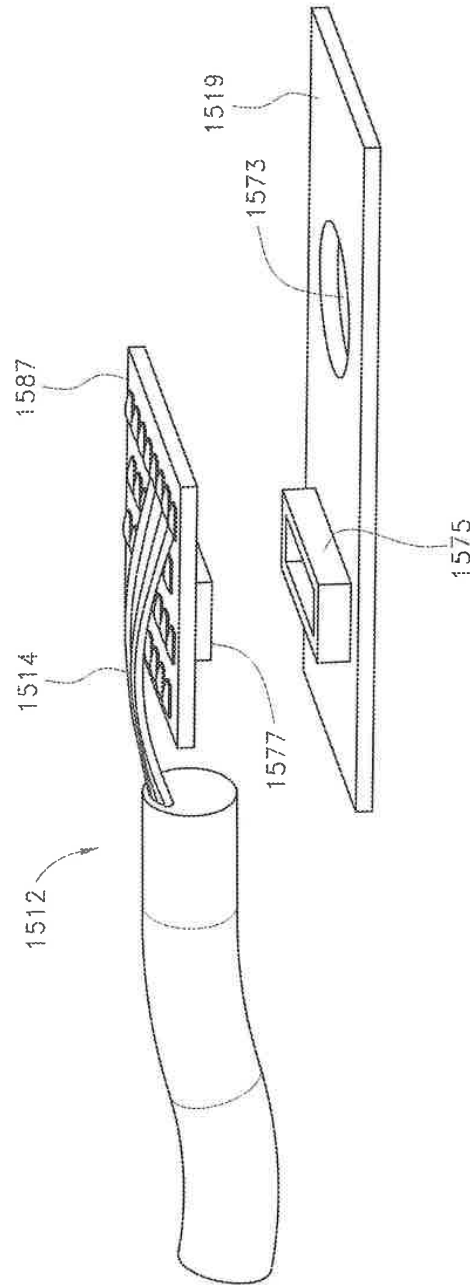


FIG. 15G

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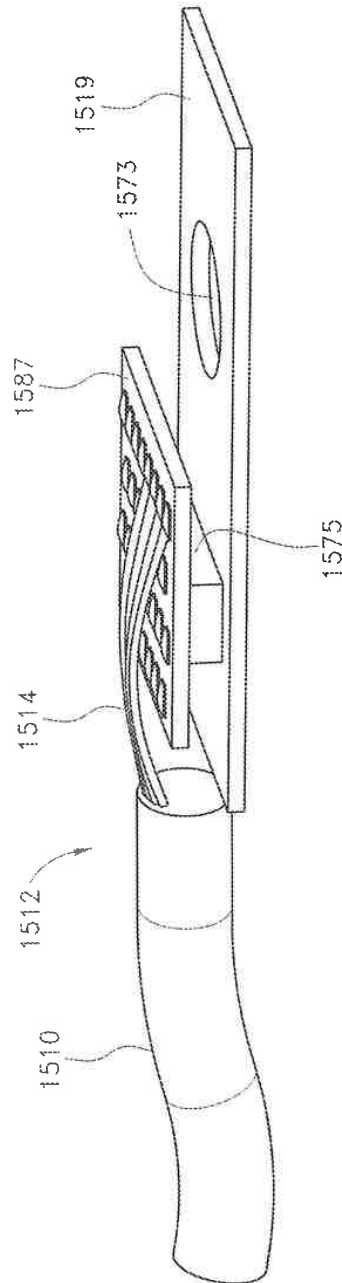


FIG. 15H

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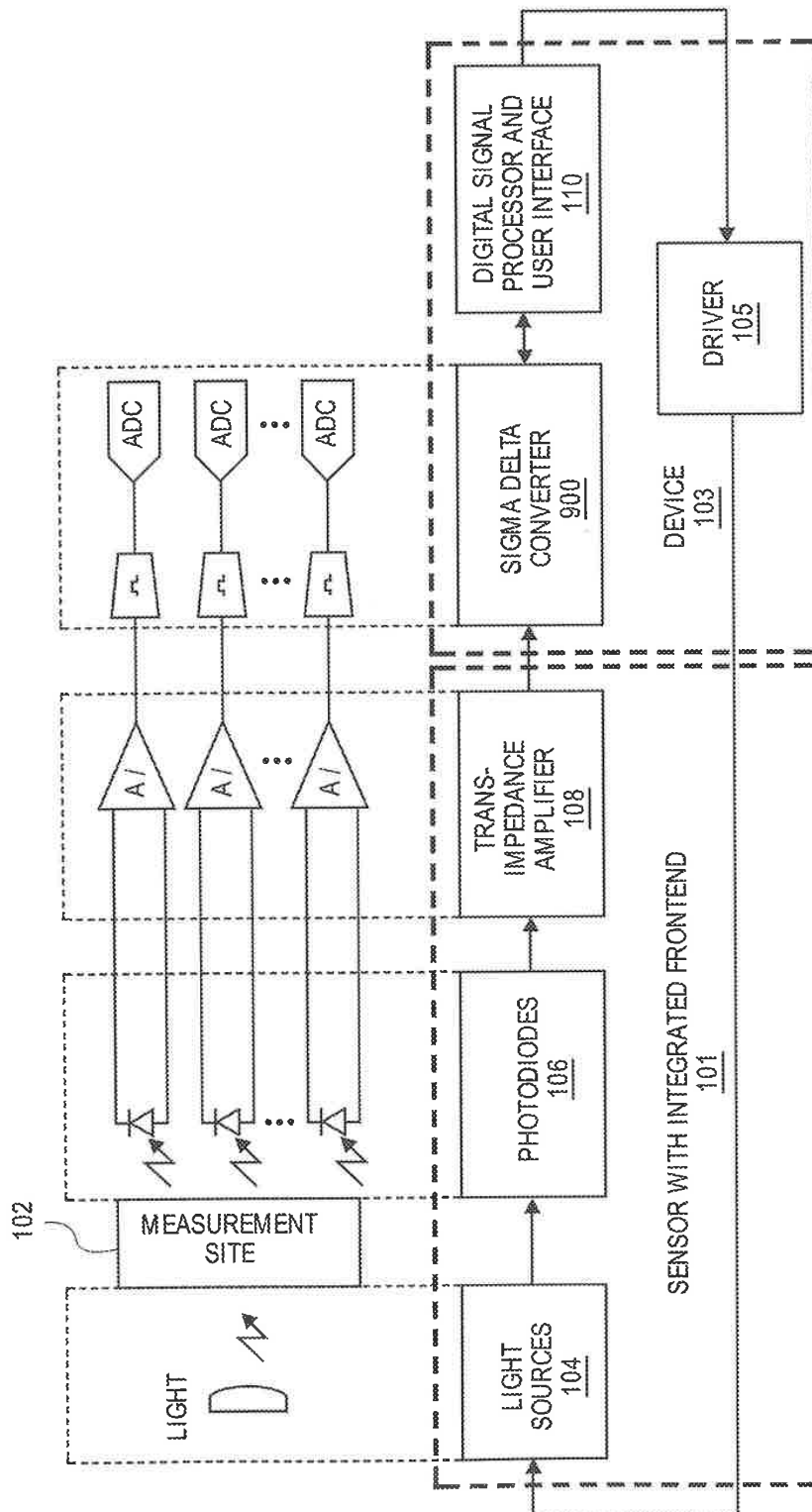


FIG. 151

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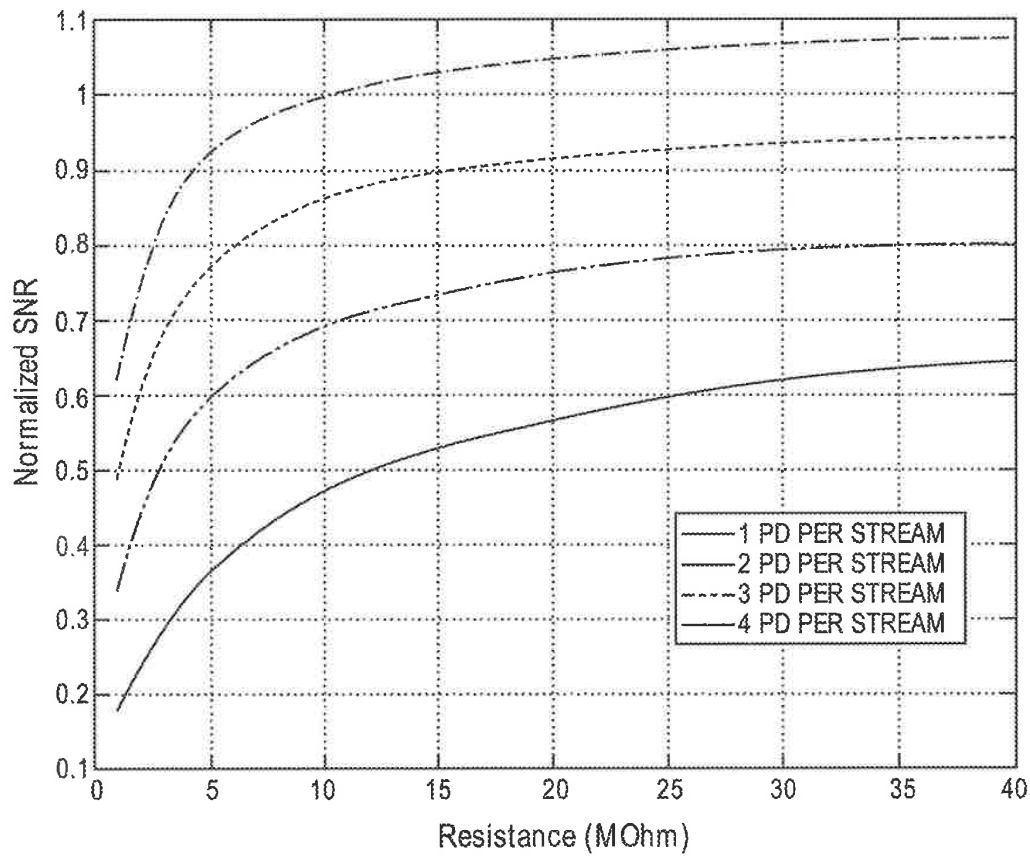


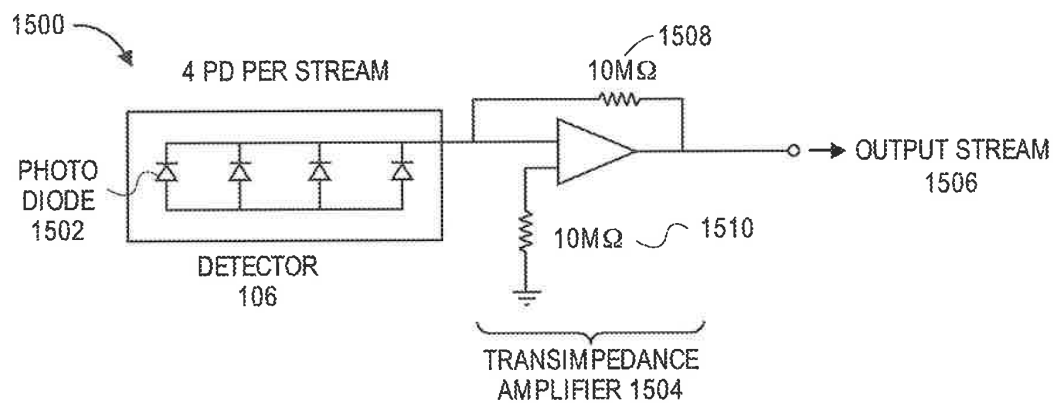
FIG. 15J

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VS.

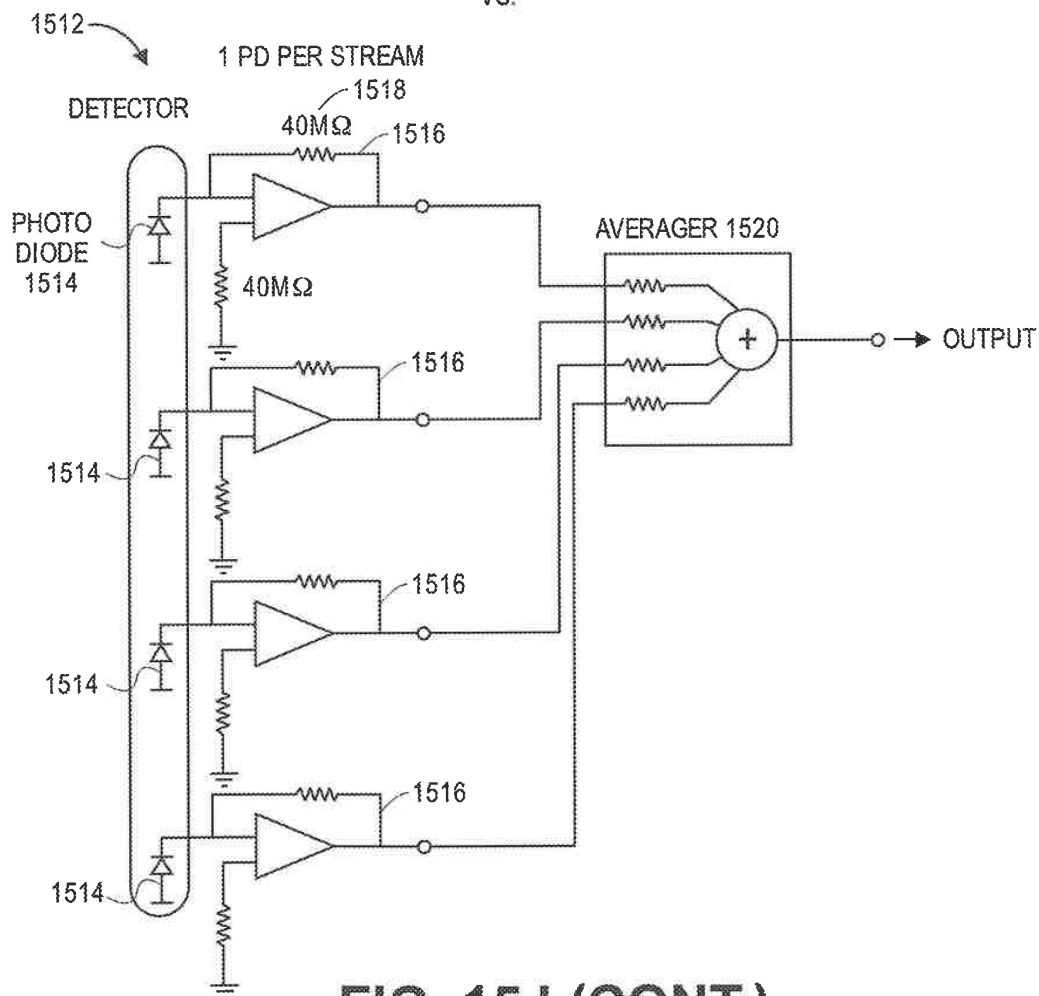


FIG. 15J (CONT.)

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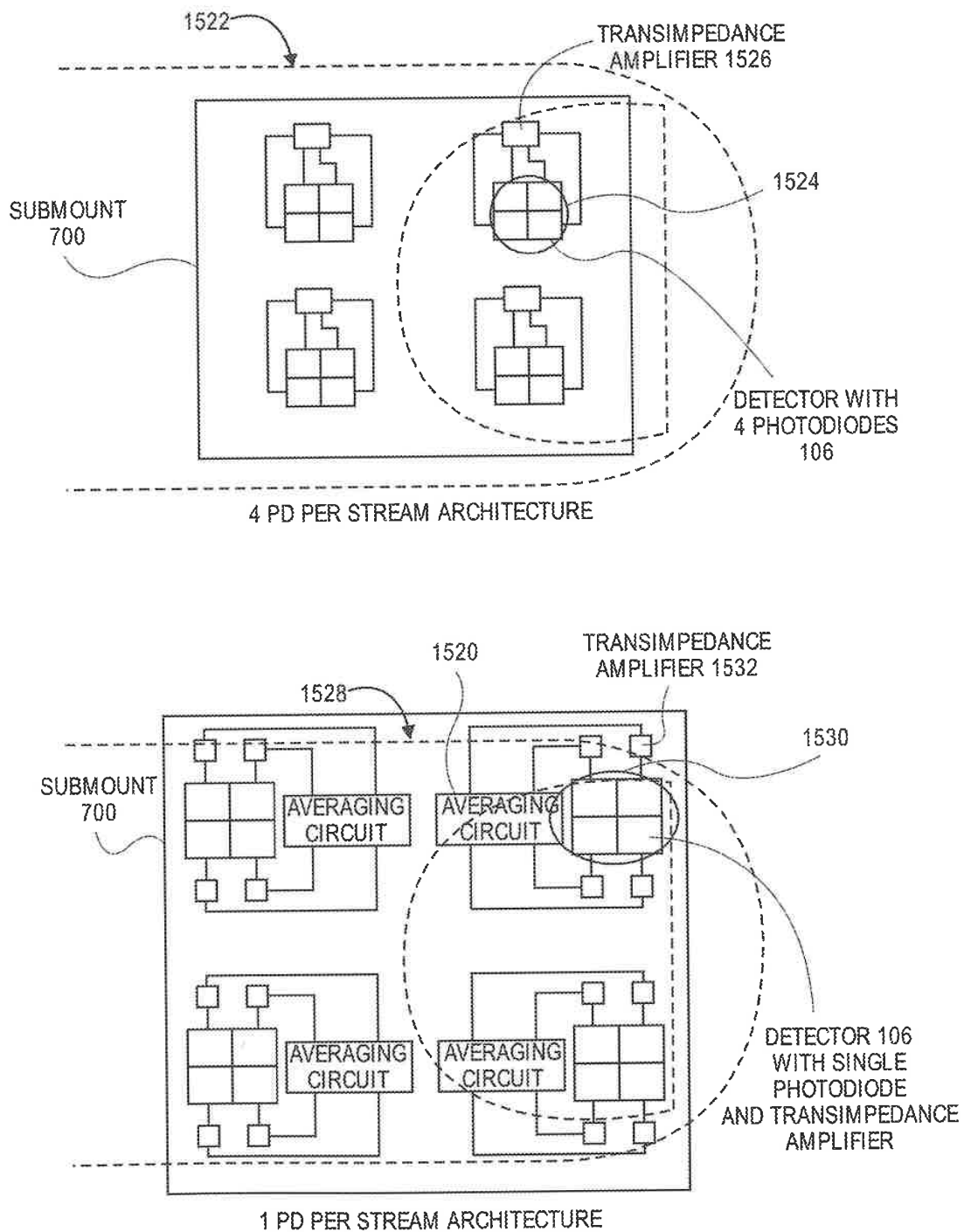


FIG. 15K

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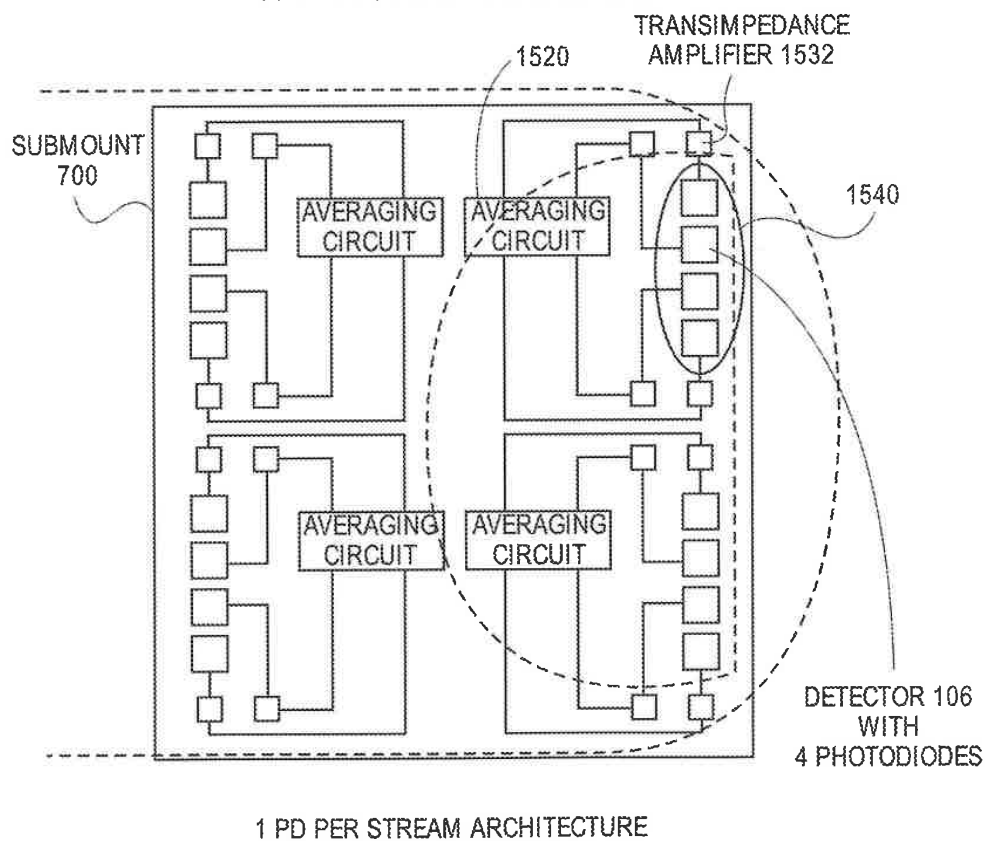
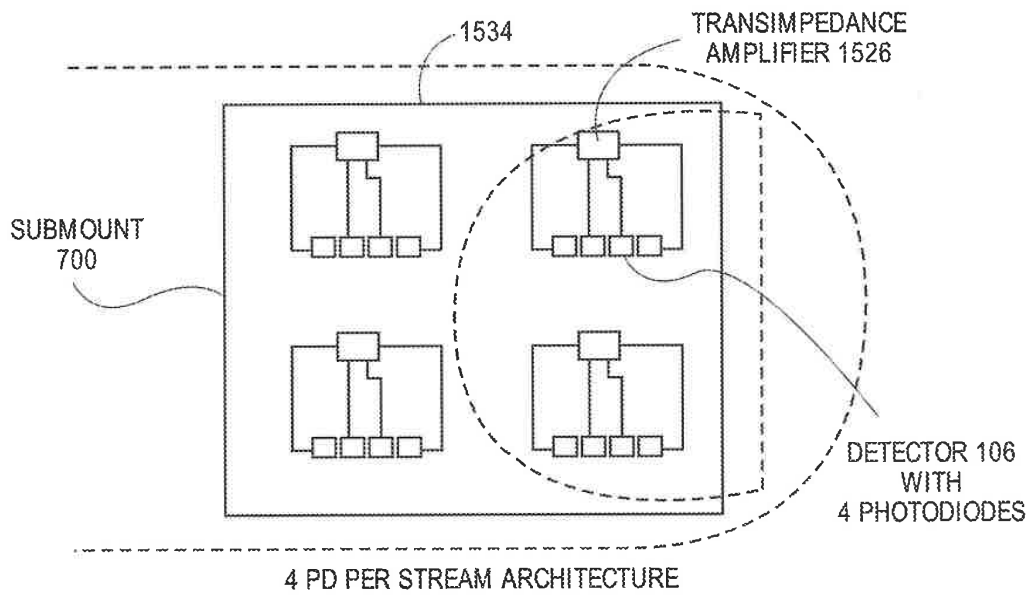


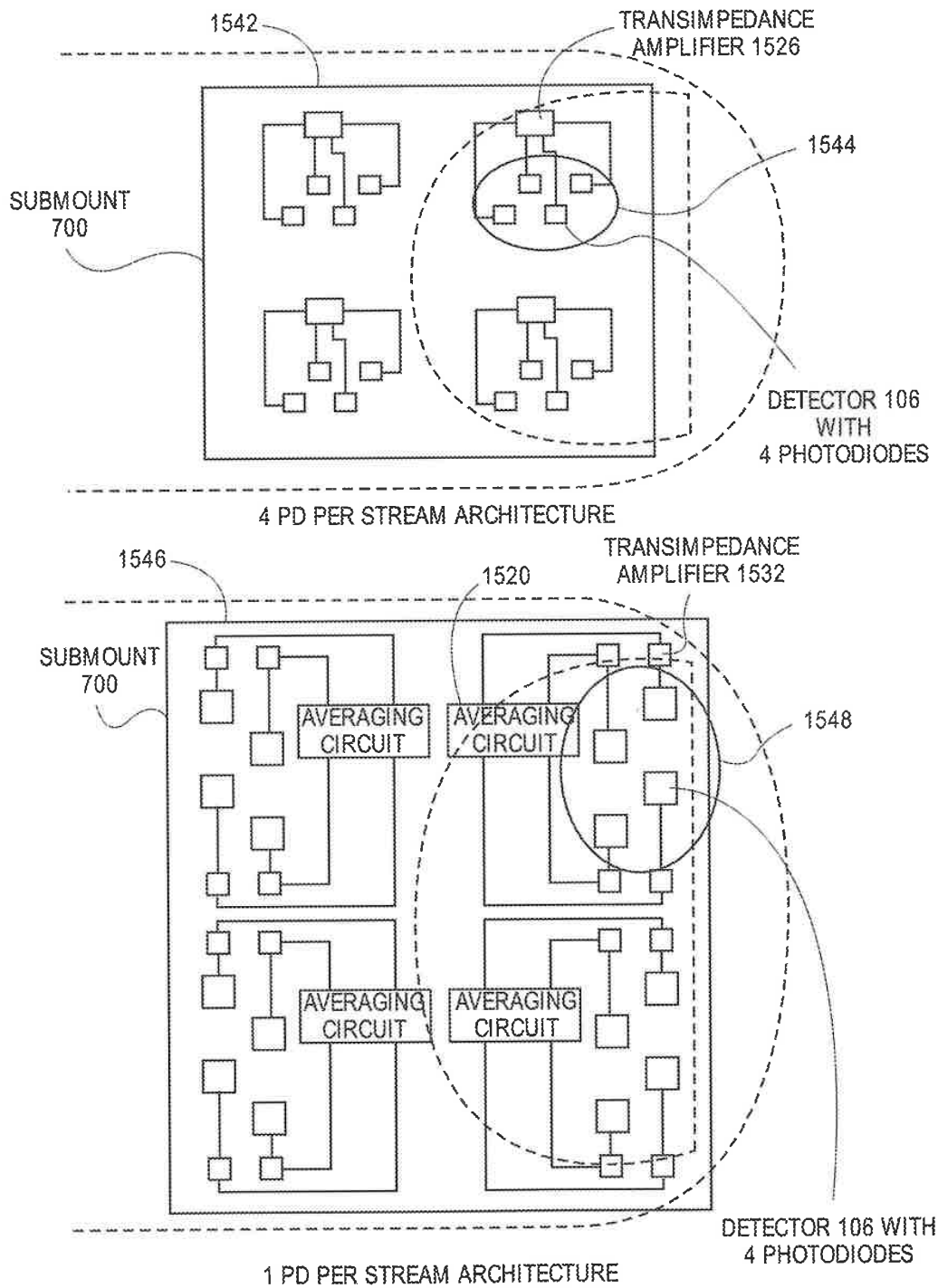
FIG. 15K (CONT.)

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**FIG. 15K (CONT.)**

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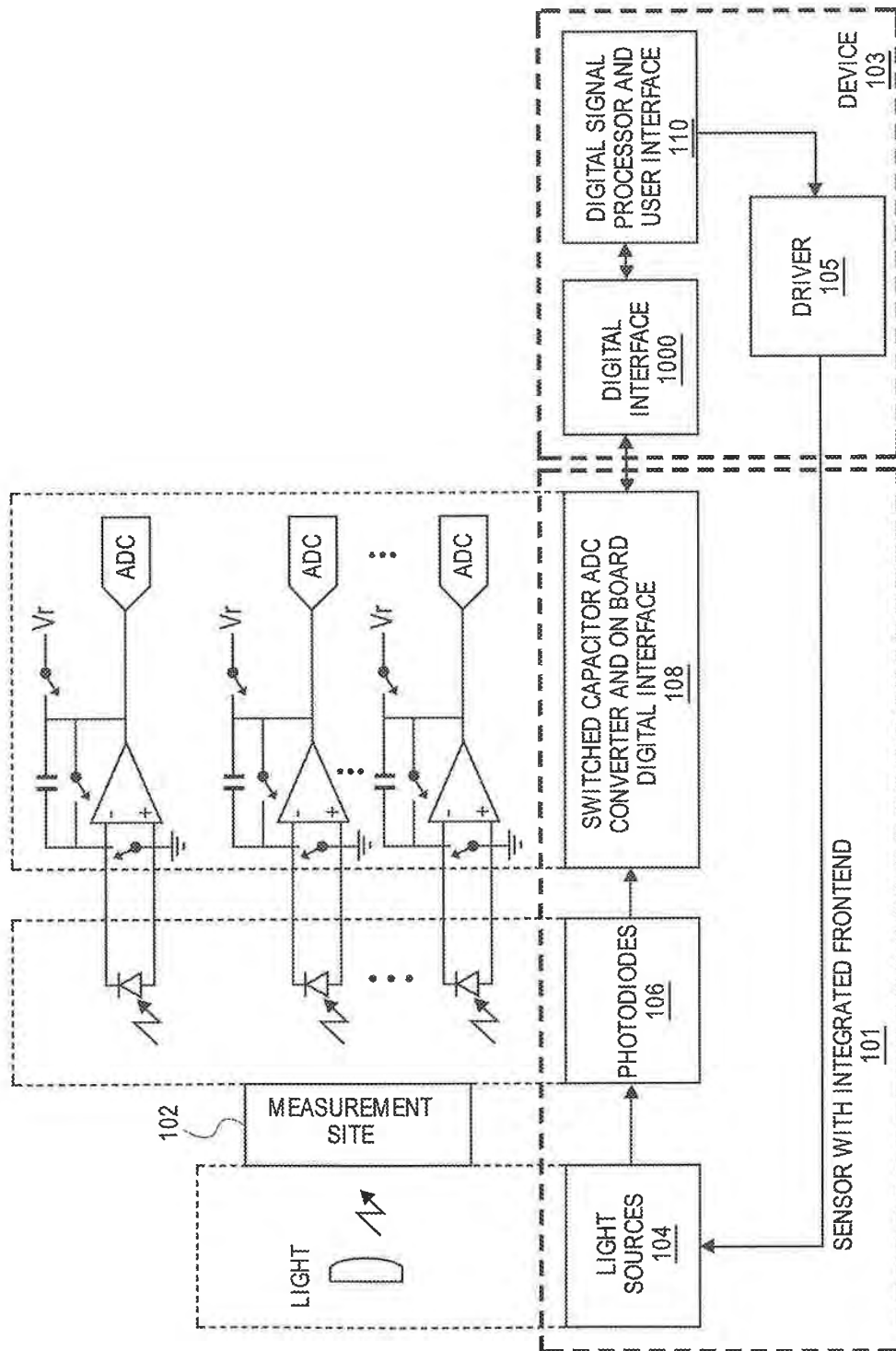


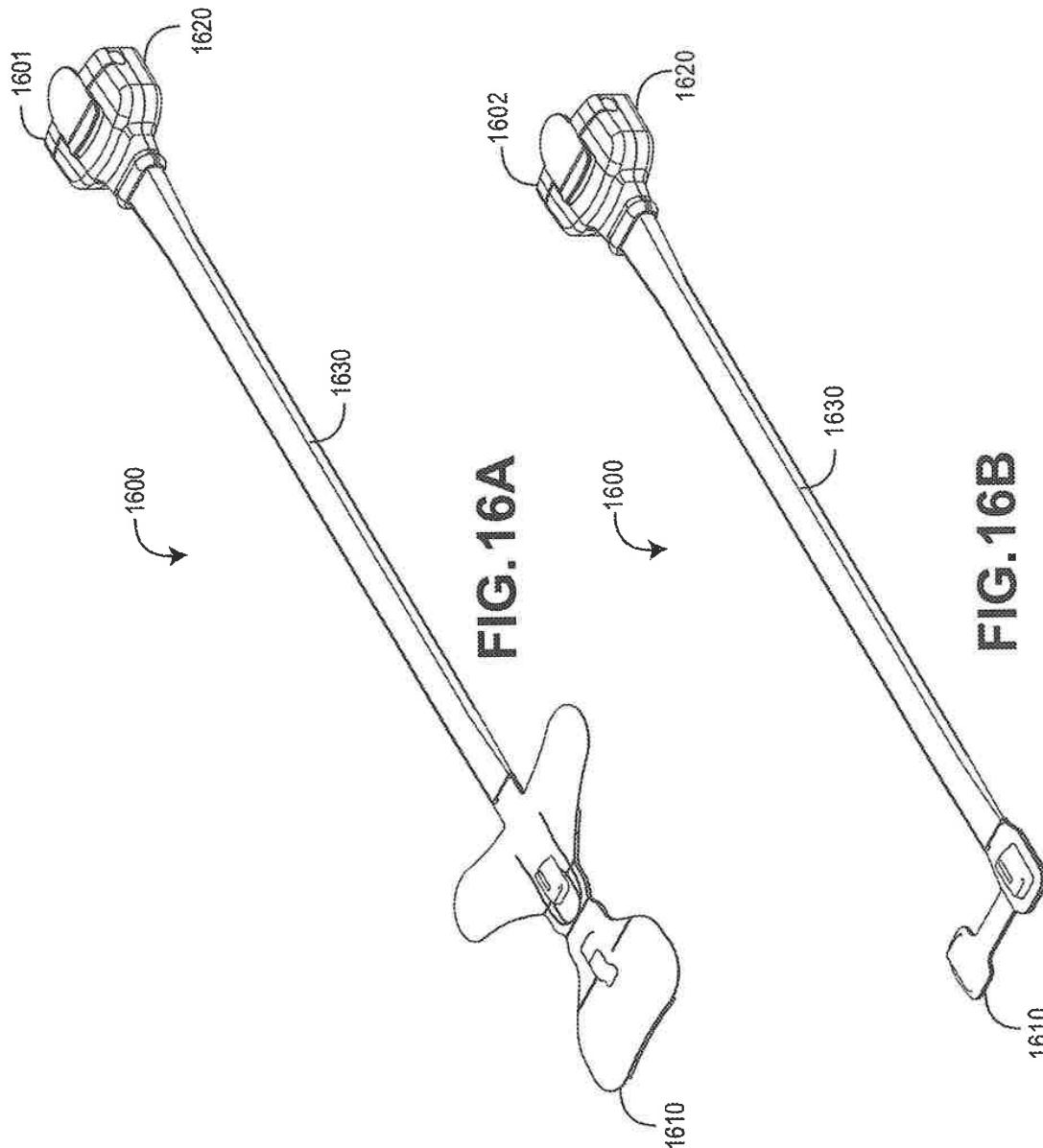
FIG. 15L

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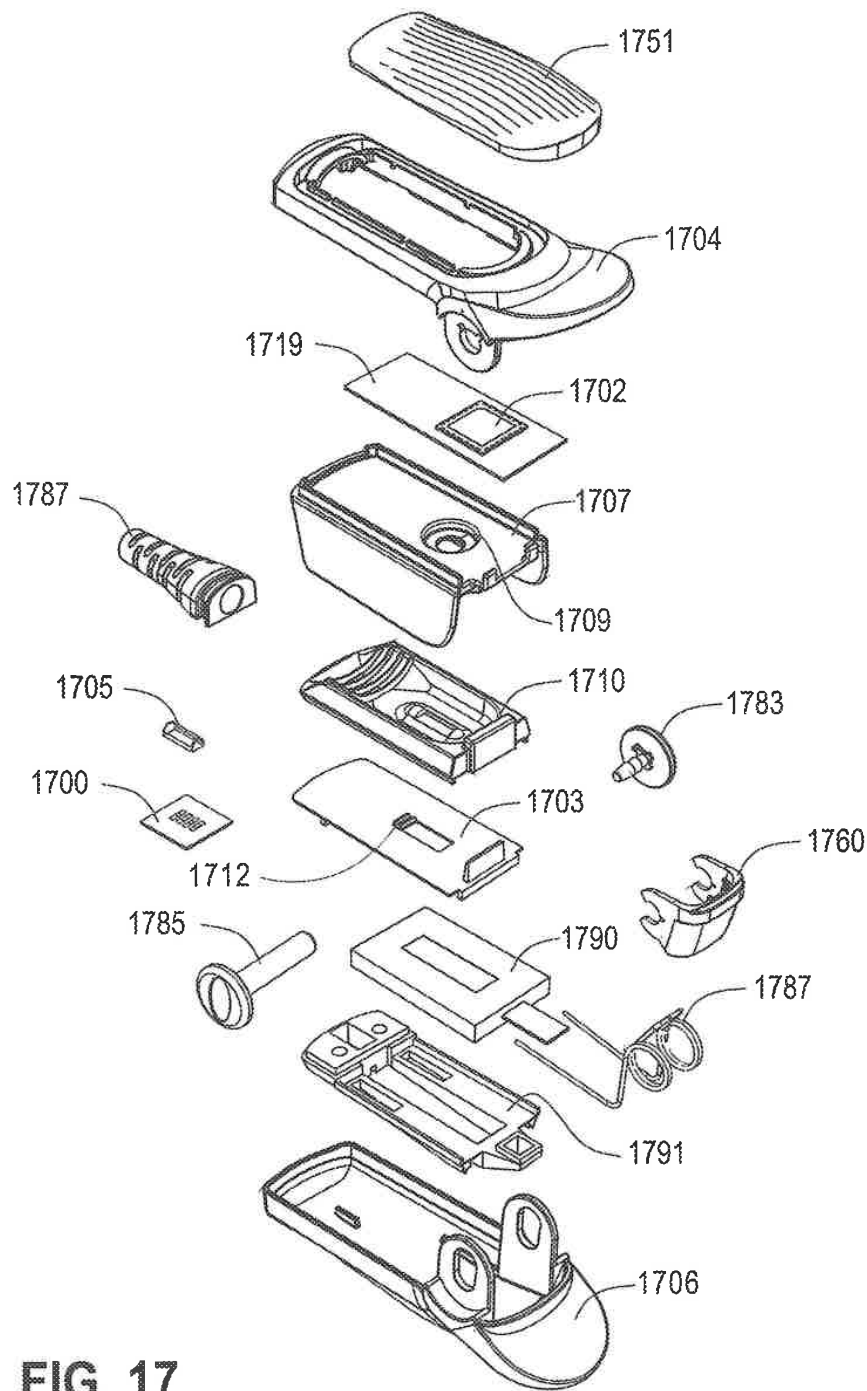


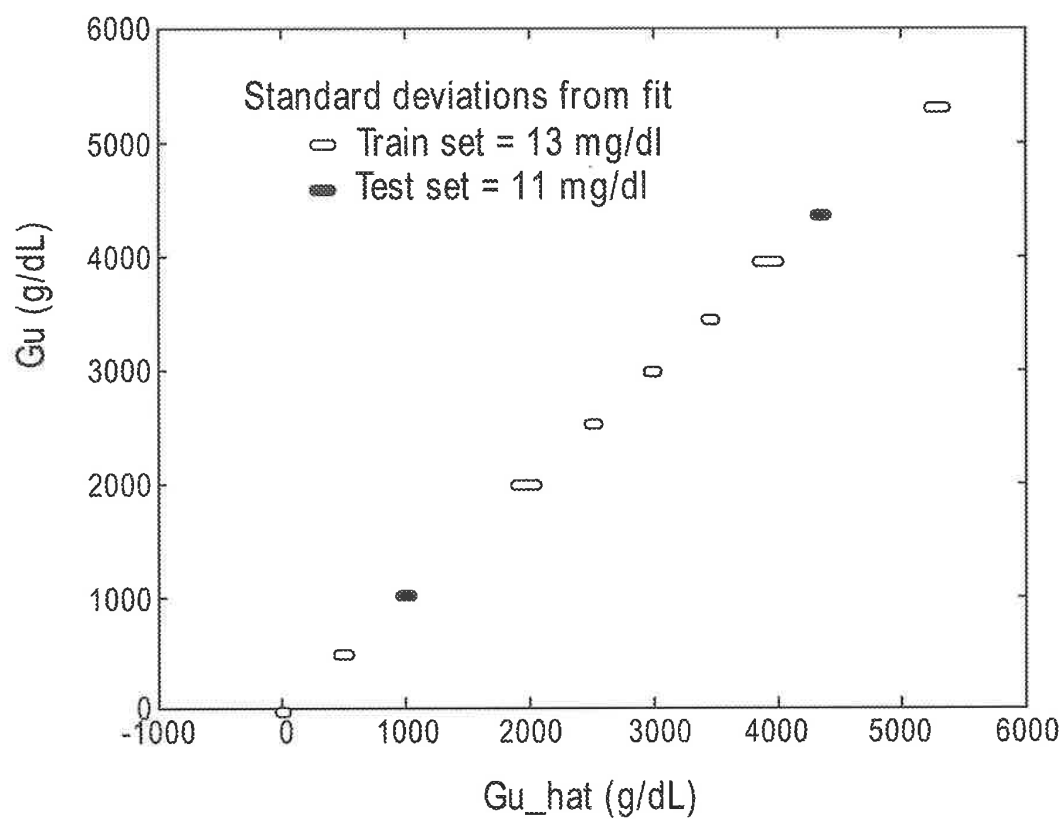
FIG. 17

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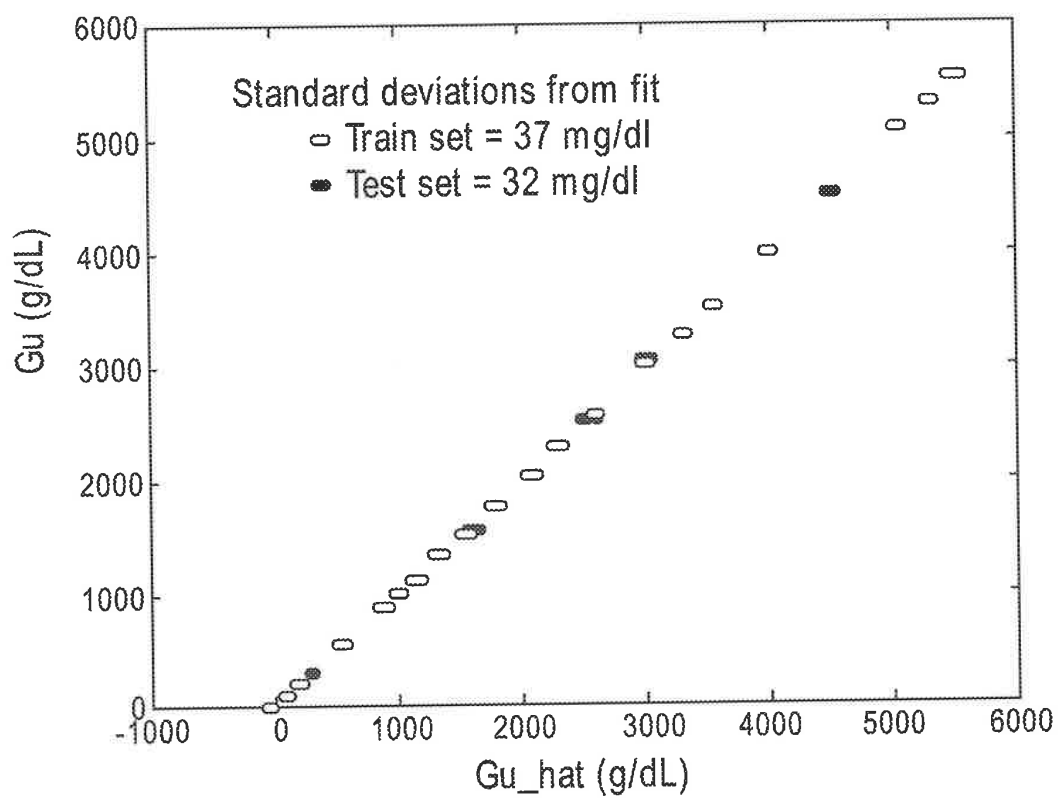
**FIG. 18**

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**FIG. 19**

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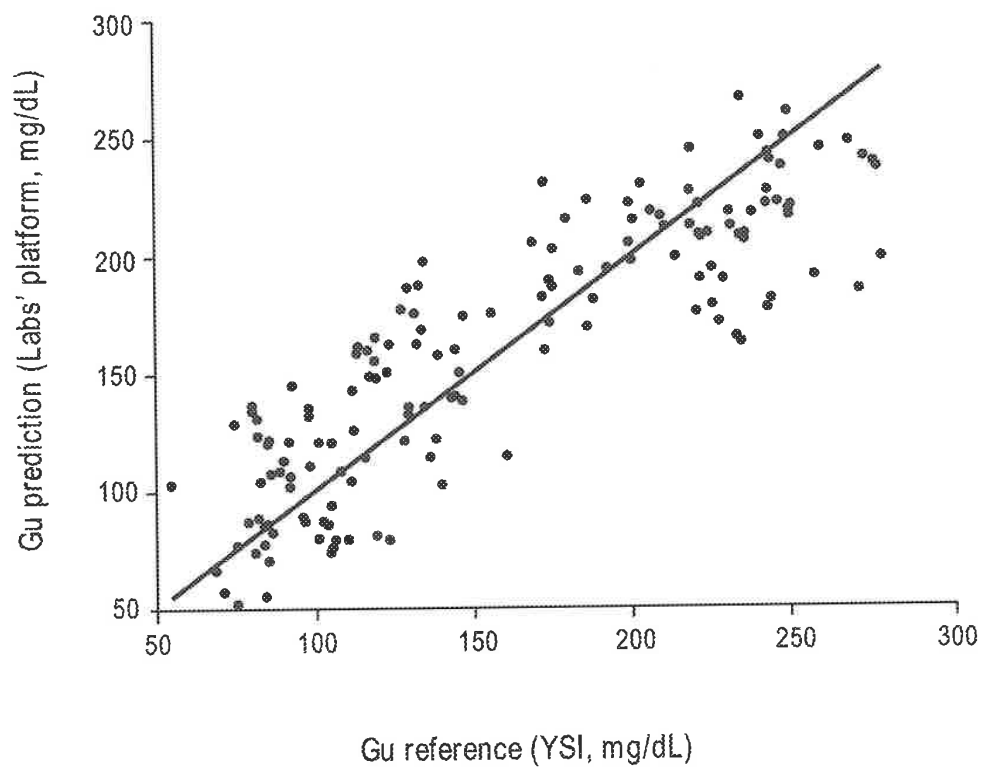


FIG. 20

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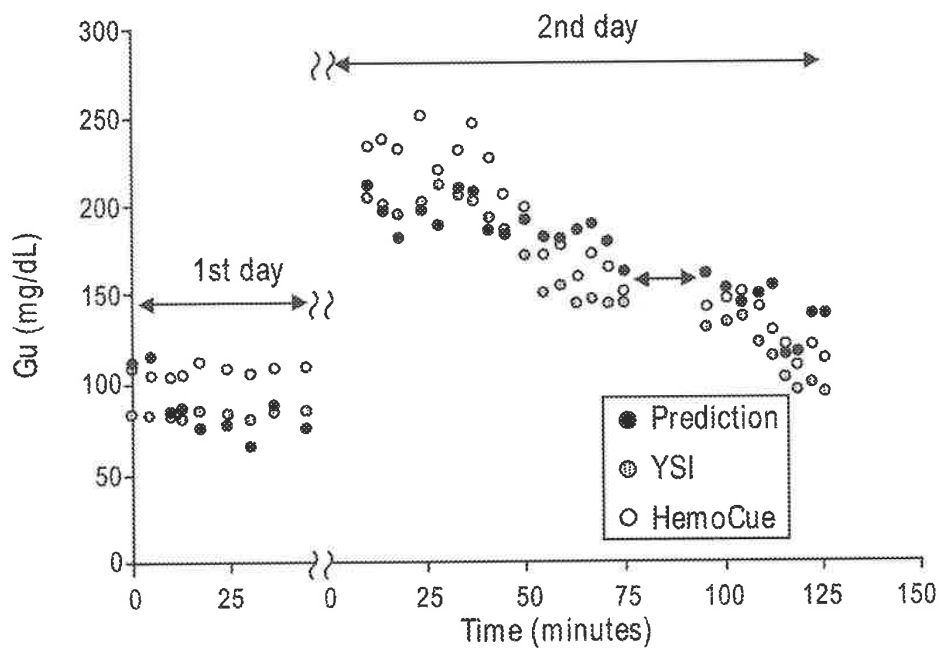


FIG. 21

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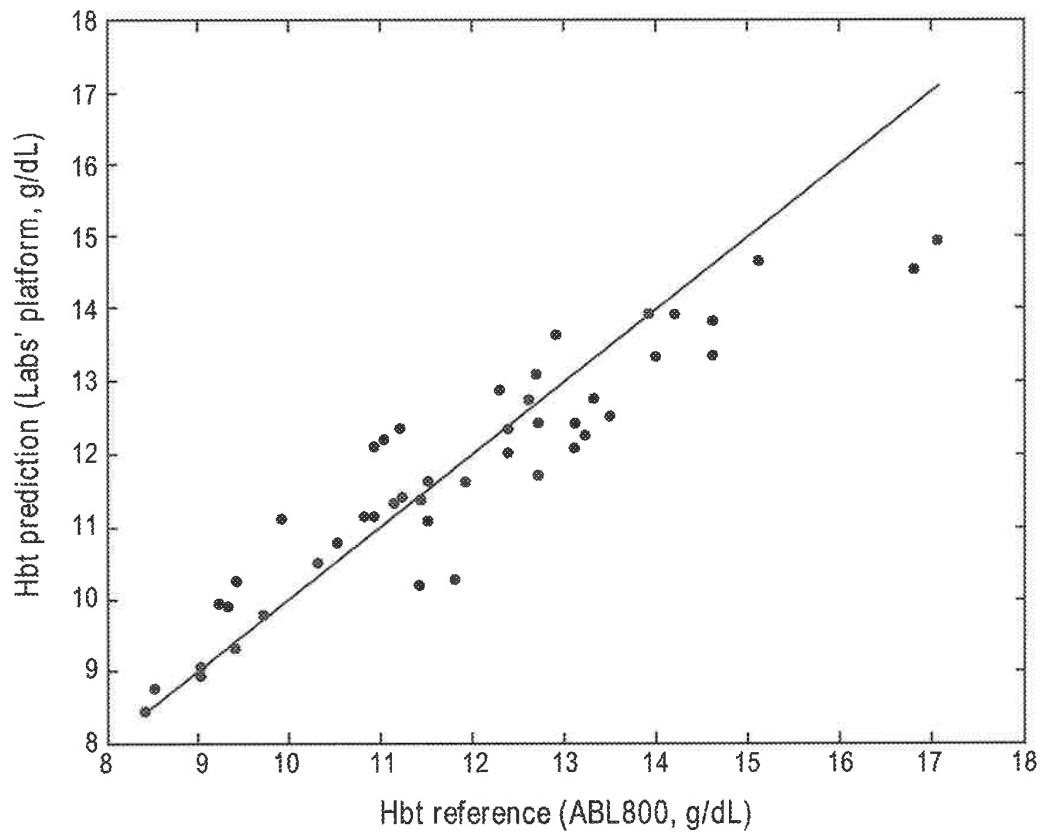


FIG. 22

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USER-WORN DEVICE FOR NONINVASIVELY MEASURING A PHYSIOLOGICAL PARAMETER OF A USER

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/834,538, filed Mar. 30, 2020, which is a continuation of U.S. patent application Ser. No. 16/725,292, filed Dec. 23, 2019, which is a continuation of U.S. patent application Ser. No. 16/534,949, filed Aug. 7, 2019, which is a continuation of U.S. patent application Ser. No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed Aug. 25, 2008 and 29/323,408 filed Aug. 25, 2008. U.S. patent application No. 12/829,352 is also a continuation-in-part of U.S. patent application No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed Aug. 25, 2008 and 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. patent applications:

application No.	Filing Date	Title
12/497,528	Jul. 2, 2009	Noise Shielding for Noninvasive Device Contoured Protusion for Improving Spectroscopic Measurement of Blood Constituents
12/497,523	Jul. 2, 2009	Heat Sink for Noninvasive Medical Sensor
12/497,506	Jul. 2, 2009	Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents
12/534,812	Aug. 3, 2009	Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents

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-continued

application No.	Filing Date	Title
12/534,825	Aug. 3, 2009	Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents

The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal(s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the non-invasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from said optical source after attenuation by the tissue of the

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measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the signals from the plurality of detectors into a digital output

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signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

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In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be reused to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. 1 illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. 2A-2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. 1, according to embodiments of the disclosure;

FIGS. 3A-3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. 3D illustrates a side view of another example non-invasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. 3E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. 3F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. 4A through 4C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

FIG. 5 illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

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FIGS. 6A through 6D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. 6E illustrates an example sensor incorporating the protrusion of FIGS. 6A through 6D, according to an embodiment of the disclosure;

FIGS. 7A through 7B illustrate example arrangements of conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIGS. 8A through 8D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIG. 9 shows example comparative results obtained by an embodiment of a sensor;

FIGS. 10A and 10B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. 11A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 12A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. 12B through 12D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. 12E through 12H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. 13 illustrates an example multi-stream operation of the system of FIG. 1, according to an embodiment of the disclosure;

FIG. 14A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion of FIG. 14A;

FIGS. 14C through 14E illustrate embodiments of a detector submount;

FIGS. 14F through 14H illustrate embodiment of portions of a detector shell;

FIG. 14I illustrates a cutaway view of an embodiment of a sensor;

FIGS. 15A through 15F illustrate embodiments of sensors that include heat sink features;

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. 15I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

FIG. 15J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. 15I;

FIG. 15K shows different architectures and layouts for various embodiments of a sensor and its detectors;

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FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors;

FIG. 17 illustrates an exploded view of certain components of an example sensor; and

FIGS. 18 through 22 illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to

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adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of non-invasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metallicized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that,

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in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in

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heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. 1 illustrates an example of a data collection system 100. In certain embodiments, the data collection system 100 noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system 100 can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system 100 can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system 100 can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm²-5 mm² (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system 100 can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system 100 can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system 100 can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system 100 can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a finger measurement site 102. However, the features of the embodiments disclosed herein can be used with other measurement sites 102.

In the depicted embodiment, the system 100 includes an optional tissue thickness adjuster or tissue shaper 105, which

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can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper 105 is a flat or substantially flat surface that can be positioned proximate the measurement site 102 and that can apply sufficient pressure to cause the tissue of the measurement site 102 to be flat or substantially flat. In other embodiments, the tissue shaper 105 is a convex or substantially convex surface with respect to the measurement site 102. Many other configurations of the tissue shaper 105 are possible. Advantageously, in certain embodiments, the tissue shaper 105 reduces thickness of the measurement site 102 while preventing or reducing occlusion at the measurement site 102. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system 100 shown also includes an optional noise shield 103. In an embodiment, the noise shield 103 can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site 102 to one or more detectors 106 (described below). For example, the noise shield 103 can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor 101 or electrically grounded. In an embodiment where the noise shield 103 includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site 102 is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system 100 can be used on a person's non-dominant hand or arm.

The data collection system 100 can include a sensor 101 (or multiple sensors) that is coupled to a processing device or physiological monitor 109. In an embodiment, the sensor 101 and the monitor 109 are integrated together into a single unit. In another embodiment, the sensor 101 and the monitor 109 are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor 101 and monitor 109 can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor 101 and the monitor 109 will now be further described.

In the depicted embodiment shown in FIG. 1, the sensor 101 includes an emitter 104, a tissue shaper 105, a set of detectors 106, and a front-end interface 108. The emitter 104 can serve as the source of optical radiation transmitted towards measurement site 102. As will be described in

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further detail below, the emitter 104 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter 104 is used as a point optical source, and thus, the one or more optical sources of the emitter 104 can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters 104 can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters 104 can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters 104.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter 104 of the data collection system 100 can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter 104 can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter 104 can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter 104 can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter 104 can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter 104 can emit optical radiation across other spectra for other analytes. In particular, the emitter 104 can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter 104 can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of

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course, the emitter 104 can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection system 100 can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source. The emitter 104 can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter 104 can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter 104 can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter 104 can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter 104 can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO₂), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter 104 can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site 102.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter 104 can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter 104 to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system 100 also includes a driver 111 that drives the emitter 104. The driver 111 can be a circuit or the like that is controlled by the monitor 109. For example, the driver 111 can provide pulses of current to the emitter 104. In an embodiment, the driver 111 drives the emitter 104 in a progressive fashion, such as in an alternating manner. The driver 111 can drive the emitter 104 with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

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The driver 111 can be synchronized with other parts of the sensor 101 and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter 104. In some embodiments, the driver 111 is capable of driving the emitter 104 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors 106 capture and measure light from the measurement site 102. For example, the detectors 106 can capture and measure light transmitted from the emitter 104 that has been attenuated or reflected from the tissue in the measurement site 102. The detectors 106 can output a detector signal 107 responsive to the light captured or measured. The detectors 106 can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors 106 can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors 106. That is, some of the detectors 106 can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter 104. However, according to an embodiment, at least some of the detectors 106 can have a different path length from the emitter 104 relative to other of the detectors 106. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors 106. In some embodiments, the detectors 106 may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface 108 provides an interface that adapts the output of the detectors 106, which is responsive to desired physiological parameters. For example, the front end interface 108 can adapt a signal 107 received from one or more of the detectors 106 into a form that can be processed by the monitor 109, for example, by a signal processor 110 in the monitor 109. The front end interface 108 can have its components assembled in the sensor 101, in the monitor 109, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface 108 can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface 108 can be coupled to the detectors 106 and to the signal processor 110 using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface 108 can also be at least partially integrated with various components, such as the detectors 106. For example, the front end interface 108 can include one or more integrated circuits that are on the same circuit board as the detectors 106. Other configurations can also be used.

The front end interface 108 can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor 109), such as a sigma-delta ADC. A transimpedance-based front end interface 108 can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface 108 can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface 108 can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter 104.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by

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the signal processor 110 of the monitor 109. Each channel can correspond to a signal output from a detector 106.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface 108. For example, the output of a transimpedance-based front end interface 108 can be output to a PGA that is coupled with an ADC in the monitor 109. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors 106. Alternatively, the PGA and ADC components can be integrated with the transimpedance-based front end interface 108 in the sensor 101.

In another embodiment, the front end interface 108 can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface 108 can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface 108 can be useful because it can provide a digital signal to the signal processor 110 in the monitor 109.

As shown in FIG. 1, the monitor 109 can include the signal processor 110 and a user interface, such as a display 112. The monitor 109 can also include optional outputs alone or in combination with the display 112, such as a storage device 114 and a network interface 116. In an embodiment, the signal processor 110 includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors 106. The signal processor 110 can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor 110 can provide various signals that control the operation of the sensor 101. For example, the signal processor 110 can provide an emitter control signal to the driver 111. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter 104. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter 104 to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface 108 is used, the control signal from the signal processor 110 can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory 113 can be included in the front-end interface 108 and/or in the signal processor 110. This memory 113 can serve as a buffer or storage location for the front-end interface 108 and/or the signal processor 110, among other uses.

The user interface 112 can provide an output, e.g., on a display, for presentation to a user of the data collection system 100. The user interface 112 can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface 112 can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface 112 can include a flip screen, a screen that can be moved from one side to another on the monitor 109, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data collection system 100 can be provided without a user interface 112 and can simply provide an output signal to a separate display or system.

A storage device 114 and a network interface 116 represent other optional output connections that can be included in the monitor 109. The storage device 114 can include any

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computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device 114, which can be executed by the signal processor 110 or another processor of the monitor 109. The network interface 116 can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor 109 to communicate and share data with other devices. The monitor 109 can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface 112, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system 100 can include various other components or can be configured in different ways. For example, the sensor 101 can have both the emitter 104 and detectors 106 on the same side of the measurement site 102 and use reflectance to measure analytes. The data collection system 100 can also include a sensor that measures the power of light emitted from the emitter 104.

FIGS. 2A through 2D illustrate example monitoring devices 200 in which the data collection system 100 can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices 200 shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system 100. In addition, certain of the features of the monitoring devices 200 shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices 200 shown.

Referring specifically to FIG. 2A, an example monitoring device 200A is shown, in which a sensor 201a and a monitor 209a are integrated into a single unit. The monitoring device 200A shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor 201a includes an emitter shell 204a and a detector shell 206a. The depicted embodiment of the monitoring device 200A also includes various control buttons 208a and a display 210a.

The sensor 201a can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector 106 by forcing light back into the sensor 201a. Pads in the emitter shell 204a and the detector shell 206a can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell 204a and the detector shell 206a can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor 201a.

In some embodiments, some or all portions of the emitter shell 204a and/or detector shell 206a can be detachable and/or disposable. For example, some or all portions of the shells 204a and 206a can be removable pieces. The removability of the shells 204a and 206a can be useful for sanitary purposes or for sizing the sensor 201a to different patients. The monitor 209a can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor 201c to be removably attached to the monitor 209a.

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The monitoring device 200a also includes optional control buttons 208a and a display 210a that can allow the user to control the operation of the device. For example, a user can operate the control buttons 208a to view one or more measurements of various analytes, such as glucose. In addition, the user can operate the control buttons 208a to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display 210a, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls 208a and/or display 210a can provide functionality for the user to manipulate settings of the monitoring device 200a, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device 200a can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. 2B illustrates another example of a monitoring device 200B. In the depicted embodiment, the monitoring device 200B includes a finger clip sensor 201b connected to a monitor 209b via a cable 212. In the embodiment shown, the monitor 209b includes a display 210b, control buttons 208b and a power button. Moreover, the monitor 209b can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor 201b, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable 212 connecting the sensor 201b and the monitor 209b can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable 212 can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor 201b to the monitor 209b. Various lengths of the cable 212 can be employed to allow for separation between the sensor 201b and the monitor 209b. The cable 212 can be fitted with a connector (male or female) on either end of the cable 212 so that the sensor 201b and the monitor 209b can be connected and disconnected from each other. Alternatively, the sensor 201b and the monitor 209b can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor 209b can be attached to the patient. For example, the monitor 209b can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor 209b can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable 212 and sensor 201b to be attached to the monitor 209b.

The monitor 209b can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor 209b can include a display 210b that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor 209b.

In addition, although a single sensor 201b with a single monitor 209b is shown, different combinations of sensors and device pairings can be implemented. For example,

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multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. 2C illustrates yet another example of monitoring device 200C that can house the data collection system 100. Like the monitoring device 200B, the monitoring device 200C includes a finger clip sensor 201c connected to a monitor 209c via a cable 212. The cable 212 can have all of the features described above with respect to FIG. 2B. The monitor 209c can include all of the features of the monitor 200B described above. For example, the monitor 209c includes buttons 208c and a display 210c. The monitor 209c shown also includes straps 214c that allow the monitor 209c to be attached to a patient's limb or the like.

FIG. 2D illustrates yet another example of monitoring device 200D that can house the data collection system 100. Like the monitoring devices 200B and 200C, the monitoring device 200D includes a finger clip sensor 201d connected to a monitor 209d via a cable 212. The cable 212 can have all of the features described above with respect to FIG. 2B. In addition to having some or all of the features described above with respect to FIGS. 2B and 2C, the monitoring device 200D includes an optional universal serial bus (USB) port 216 and an Ethernet port 218. The USB port 216 and the Ethernet port 218 can be used, for example, to transfer information between the monitor 209d and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor 209b, and perform a variety of other functions. The USB port 216 and the Ethernet port 218 can be included with the other monitoring devices 200A, 200B, and 200C described above.

FIGS. 3A through 3C illustrate more detailed examples of embodiments of a sensor 301a. The sensor 301a shown can include all of the features of the sensors 100 and 200 described above.

Referring to FIG. 3A, the sensor 301a in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure 302a for receiving a patient's finger. The enclosure 302a is formed by an upper section or emitter shell 304a, which is pivotably connected with a lower section or detector shell 306a. The emitter shell 304a can be biased with the detector shell 306a to close together around a pivot point 303a and thereby sandwich finger tissue between the emitter and detector shells 304a, 306a.

In an embodiment, the pivot point 303a advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells 304a, 306a to effectively level the sections when applied to a tissue site. In another embodiment, the sensor 301a includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell 304a can position and house various emitter components of the sensor 301a. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metalicized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell 304a can also include absorbing opaque material, such as, for example, black or grey colored material, at various areas, such as on one or more flaps 307a, to reduce ambient light entering the sensor 301a.

The detector shell 306a can position and house one or more detector portions of the sensor 301a. The detector shell 306a can be constructed of reflective material, such as white

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silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. 1). The detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308a, to reduce ambient light entering the sensor 301a.

Referring to FIGS. 3B and 3C, an example of finger bed 310 is shown in the sensor 301b. The finger bed 310 includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

Finger bed 310 can also include an embodiment of a tissue thickness adjuster or protrusion 305. The protrusion 305 includes a measurement site contact area 370 (see FIG. 3C) that can contact body tissue of a measurement site. The protrusion 305 can be removed from or integrated with the finger bed 310. Interchangeable, different shaped protrusions 305 can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. 3C, the contact area 370 of the protrusion 305 can include openings or windows 320, 321, 322, and 323. When light from a measurement site passes through the windows 320, 321, 322, and 323, the light can reach one or more photodetectors (see FIG. 3E). In an embodiment, the windows 320, 321, 322, and 323 mirror specific detector placements layouts such that light can impinge through the protrusion 305 onto the photodetectors. Any number of windows 320, 321, 322, and 323 can be employed in the protrusion 305 to allow light to pass from the measurement site to the photodetectors.

The windows 320, 321, 322, and 323 can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows 320, 321, 322, and 323 can be made from materials, such as plastic or glass. In some embodiments, the windows 320, 321, 322, and 323 can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

Turning to FIG. 3B, the sensor 301a can also include a shielding 315a, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding 315a is provided in the depicted embodiment below or embedded within the protrusion 305 to reduce noise. The shielding 315a can be constructed from a conductive material, such as copper. The

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shielding 315a can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the windows 320, 321, 322, and 323 on an external surface of the protrusion 305 (see FIG. 3C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. 3E).

In some embodiments, the shielding cage for shielding 315a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion 305 (see FIG. 3E).

In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion 305 can be selected. In making such determinations, consideration can be made of protrusion's 305 effect on blood flow at the measurement site and mean path length for optical radiation passing through openings 320, 321, 322, and 323. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion 305 can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area 370 to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion 305 can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area 370. The contact area 370 can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion 305 can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion 305 and the contact area 370 can include a combination of materials with various characteristics.

The contact area 370 serves as a contact surface for the measurement site. For example, in some embodiments, the contact area 370 can be shaped for contact with a patient's finger. Accordingly, the contact area 370 can be sized and shaped for different sizes of fingers. The contact area 370 can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example, the contact area 370 can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. 5 provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

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Referring to FIG. 5, a plot 500 is shown that illustrates examples of effects of embodiments of the protrusion 305 on the SNR at various wavelengths of light. As described above, the protrusion 305 can assist in conforming the tissue and effectively reduce its mean path length. In some instances, this effect by the protrusion 305 can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I = I_0 * e^{-m * b * c}$, where I_0 is the initial power of light being transmitted, m is the path length traveled by the light, and the component " $b * c$ " corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1} . Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I = I_0 * e^{(-20 * 0.7)}$.

In an embodiment where the protrusion 305 is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box 510). This results in a new transmittance, $I_1 = I_0 * e^{(-16.6 * 0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot 500 of FIG. 5. The plot 500 illustrates potential effects of the protrusion 305 on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6 * 0.7)} / e^{(-20 * 0.7)}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1} . The plot 500 also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. 3A through 3C, an example heat sink 350a is also shown. The heat sink 350a can be attached to, or protrude from an outer surface of, the sensor 301a, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor 301a in certain embodiments, the heat sink 350a can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. 1) generate sufficient heat that inclusion of the heat sink 350a can advantageously allow the sensor 301a to remain safely cooled. The heat sink 350a can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell 304a can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink 350a includes metalized plastic. The metalized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink 350a can include a thermally conductive liquid crystalline polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, Rhode Island. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink 350a provides improved heat transfer properties when the sensor 301a is active for short intervals of less than a full day's use. In an embodiment, the heat sink 350a can

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advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink 350a can be selected that performs effectively in shorter or longer intervals.

Moreover, the heat sink 350a can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink 350a is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink 350a shown includes fins 351a (see FIG. 3A).

An alternative shape of a sensor 301b and heat sink 350b is shown in FIG. 3D. The sensor 301b can include some or all of the features of the sensor 301a. For example, the sensor 301b includes an enclosure 302b formed by an emitter shell 304b and a detector shell 306b, pivotably connected about a pivot 303a. The emitter shell 304b can also include absorbing opaque material on one or more flaps 307b, and the detector shell 306a can also include absorbing opaque material at various areas, such as lower area 308b.

However, the shape of the sensor 301b is different in this embodiment. In particular, the heat sink 350b includes comb protrusions 351b. The comb protrusions 351b are exposed to the air in a similar manner to the fins 351a of the heat sink 350a, thereby facilitating efficient cooling of the sensor 301b.

FIG. 3E illustrates a more detailed example of a detector shell 306b of the sensor 301b. The features described with respect to the detector shell 306b can also be used with the detector shell 306a of the sensor 301a.

As shown, the detector shell 306b includes detectors 316. The detectors 316 can have a predetermined spacing 340 from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors 316 and the emitter discussed above.

In the depicted embodiment, the detector shell 316 can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site 102). In the detector shell 316, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell 316 can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. 3E, the detectors 316 can have a spatial configuration of a grid. However, the detectors 316 can be arranged in other configurations that vary the path length. For example, the detectors 316 can be arranged in a linear array, a logarithmic array, a two-dimensional array, a zig-zag pattern, or the like. Furthermore, any number of the detectors 316 can be employed in certain embodiments.

FIG. 3F illustrates another embodiment of a sensor 301f. The sensor 301f can include some or all of the features of the sensor 301a of FIG. 3A described above. For example, the sensor 301f includes an enclosure 302f formed by an upper section or emitter shell 304f, which is pivotably connected

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with a lower section or detector shell 306f around a pivot point 303f. The emitter shell 304f can also include absorbing opaque material on various areas, such as on one or more flaps 307f, to reduce ambient light entering the sensor 301f. The detector shell 306f can also include absorbing opaque material at various areas, such as a lower area 308f. The sensor 301f also includes a heat sink 350f, which includes fins 351f.

In addition to these features, the sensor 301f includes a flex circuit cover 360, which can be made of plastic or another suitable material. The flex circuit cover 360 can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell 304f to the detector shell 306f. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. 46 and associated description, which is hereby specifically incorporated by reference). The flex circuit cover 360 is shown in more detail below in FIG. 17.

In addition, sensors 301a-f has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. 4A through 4C illustrate example arrangements of a protrusion 405, which is an embodiment of the protrusion 305 described above. In an embodiment, the protrusion 405 can include a measurement site contact area 470. The measurement site contact area 470 can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion 405 can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion 405 can have a length 400, a width 410, and a height 430. The length 400 can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width 410 can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area 470 can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site. The measurement site contact area 470 can be other shapes that reduce or even minimize air between the protrusion 405 and/or the measurement site. Additionally, the surface pattern of the measurement site contact area 470 can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. 4A and 4C, openings or windows 420, 421, 422, and 423 can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows 420, 421, 422, and 423 can be of non-uniform shapes and sizes. As shown, the windows 420, 421, 422, and 423 can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of arranging the windows 420, 421, 422, and 423 are possible. For example, the windows 420, 421, 422, and 423 can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows 420, 421, 422, and 423 can be placed at different heights with respect to the finger bed 310 of FIG. 3. The windows 420, 421, 422, and 423 can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

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FIGS. 6A through 6D illustrate another embodiment of a protrusion 605 that can be used as the tissue shaper 105 described above or in place of the protrusions 305, 405 described above. The depicted protrusion 605 is a partially cylindrical lens having a partial cylinder 608 and an extension 610. The partial cylinder 608 can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion 605 focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. 6A illustrates a perspective view of the partially cylindrical protrusion 605. FIG. 6B illustrates a front elevation view of the partially cylindrical protrusion 605. FIG. 6C illustrates a side view of the partially cylindrical protrusion 605. FIG. 6D illustrates a top view of the partially cylindrical protrusion 605.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion 605 over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion 605 penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion 605 can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion 605 can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. 14). If fewer or smaller photodiodes are used, the partially cylindrical protrusion 605 can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion 605 can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. 6C, the overall height of the partially cylindrical protrusion 605 (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion 605 to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion 605 can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion 605 is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. 6D, the width of the partially cylindrical protrusion 605 (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration of the partially cylindrical protrusion 605 into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion 605 can also accomplish this objective. For example, the width of the partially cylindrical protrusion 605 can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion 605 could

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be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially cylindrical protrusion 605 can be expressed as:

$$f = \frac{R}{n-1},$$

where R is the radius of curvature of the partial cylinder 608 and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion 605 can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion 605 having a material with a higher index of refraction such as nSF11 glass (e.g., $n=1.75$ at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion 605 can be chosen to improve or optimize the light focusing properties of the protrusion 605. A plastic partially cylindrical protrusion 605 could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion 605.

Placing a photodiode at a given distance below the partially cylindrical protrusion 605 can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. 14). Different sizes of the partially cylindrical protrusion 605 can use different sizes of photodiodes. The extension 610 added onto the bottom of the partial cylinder 608 is used in certain embodiments to increase the height of the partially cylindrical protrusion 605. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion 605. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension 610 can also further facilitate the protrusion 605 increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension 610 can be omitted.

FIG. 6E illustrates another view of the sensor 301f of FIG. 3F, which includes an embodiment of a partially cylindrical protrusion 605b. Like the sensor 301A shown in FIGS. 3B and 3C, the sensor 301f includes a finger bed 310f. The finger bed 310f includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310f also includes the ridges or channels 314 described above with respect to FIGS. 3B and 3C.

The example of finger bed 310f shown also includes the protrusion 605b, which includes the features of the protrusion 605 described above. In addition, the protrusion 605b also includes chamfered edges 607 on each end to provide a more comfortable surface for a finger to slide across (see

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also FIG. 14D). In another embodiment, the protrusion 605b could instead include a single chamfered edge 607 proximal to the ridges 314. In another embodiment, one or both of the chamfered edges 607 could be rounded.

The protrusion 605b also includes a measurement site contact area 670 that can contact body tissue of a measurement site. The protrusion 605b can be removed from or integrated with the finger bed 310f. Interchangeable, differently shaped protrusions 605b can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. 7A and 7B illustrate block diagrams of sensors 701 that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above. Although not shown, the partially cylindrical protrusion 605 of FIG. 6 can also be used with the sensors 701 in certain embodiments.

For example, referring specifically to FIG. 7A, the sensor 701a includes an emitter housing 704a and a detector housing 706. The emitter housing 704a includes LEDs 104. The detector housing 706a includes a tissue bed 710a with an opening or window 703a, the conductive glass 730a, and one or more photodiodes for detectors 106 provided on a submount 707a.

During operation, a finger 102 can be placed on the tissue bed 710a and optical radiation can be emitted from the LEDs 104. Light can then be attenuated as it passes through or is reflected from the tissue of the finger 102. The attenuated light can then pass through the opening 703a in the tissue bed 710a. Based on the received light, the detectors 106 can provide a detector signal 107, for example, to the front end interface 108 (see FIG. 1).

In the depicted embodiment, the conductive glass 730 is provided in the opening 703. The conductive glass 730 can thus not only permit light from the finger to pass to the detectors 106, but it can also supplement the shielding of the detectors 106 from noise. The conductive glass 730 can include a stack or set of layers. In FIG. 7A, the conductive glass 730a is shown having a glass layer 731 proximate the finger 102 and a conductive layer 733 electrically coupled to the shielding 790a.

In an embodiment, the conductive glass 730a can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure 790a, the conductive glass 730a can be electrically coupled to the shielding enclosure 790a. The conductive glass 730a can be electrically coupled to the shielding 704a based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure 790a can be provided to encompass the detectors 106 to reduce or prevent noise. For example, the shielding enclosure 790a can be constructed from a conductive material, such as copper, in the form of a metal cage. The shielding or enclosure a can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

In some embodiments, the shielding enclosure 790a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790a can also be used

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to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

Referring to FIG. 7B, another block diagram of an example sensor 701b is shown. A tissue bed 710b of the sensor 701b includes a protrusion 705b, which is in the form of a convex bump. The protrusion 705b can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion 705b includes a contact area 370 that comes in contact with the finger 102 and which can include one or more openings 703b. One or more components of conductive glass 730b can be provided in the openings 703. For example, in an embodiment, each of the openings 703 can include a separate window of the conductive glass 730b. In an embodiment, a single piece of the conductive glass 730b can be used for some or all of the openings 703b. The conductive glass 730b is smaller than the conductive glass 730a in this particular embodiment.

A shielding enclosure 790b is also provided, which can have all the features of the shielding enclosure 790a. The shielding enclosure 790b is smaller than the shielding enclosure 790a; however, a variety of sizes can be selected for the shielding enclosures 790.

In some embodiments, the shielding enclosure 790b can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure 790b can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

FIGS. 8A through 8D illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors 701a, 701b. As shown in the perspective view of FIG. 8A and side view of FIG. 8B, the conductive glass 730 includes the electrically conductive material 733 described above as a coating on the glass layer 731 described above to form a stack. In an embodiment where the electrically conductive material 733 includes indium tin oxide, surface resistivity of the electrically conductive material 733 can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material 733.

Although the conductive material 733 is shown spread over the surface of the glass layer 731, the conductive material 733 can be patterned or provided on selected portions of the glass layer 731. Furthermore, the conductive material 733 can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. 8C, a side view of a conductive glass 830a is shown to illustrate an embodiment where the electrically conductive material 733 is provided as an internal layer between two glass layers 731, 835. Various combinations of integrating electrically conductive material 733 with glass are possible. For example, the electrically conductive material 733 can be a layer within a stack of layers. This stack of layers can include one or more layers of glass 731, 835, as well as one or more layers of conductive material 733. The stack can include other layers of materials to achieve desired characteristics.

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In FIG. 8D, a bottom perspective view is shown to illustrate an embodiment where a conductive glass 830b can include conductive material 837 that occupies or covers a portion of a glass layer 839. This embodiment can be useful, for example, to create individual, shielded windows for detectors 106, such as those shown in FIG. 3C. The conductive material 837 can be patterned to include an area 838 to allow light to pass to detectors 106 and one or more strips 841 to couple to the shielding 704 of FIG. 7.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. 9 depicts an example graph 900 that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. 7 and 8. The graph 900 depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line 915 on the graph 900 illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line 920 on the graph 900 demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line 925 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line 930 on the graph 900 shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. 10A through 10B illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. 10A, a graph 1000 depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above included separate windows for four (4) detectors 106. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols 1030-1033 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. 10B, a graph 1050 depicts a noise floor for frequencies of noise 1070 for an embodiment in which the sensor included separate openings for four (4) detectors 106

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and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols 1080-1083 illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodiment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. 10A.

FIG. 11A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter 104 can include a driver 1105, a thermistor 1120, a set of top-emitting LEDs 1102 for emitting red and/or infrared light, a set of side-emitting LEDs 1104 for emitting near infrared light, and a submount 1106.

The thermistor 1120 can be provided to compensate for temperature variations. For example, the thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement site. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver 1105 can provide pulses of current to the emitter 1104. In an embodiment, the driver 1105 drives the emitter 1104 in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor 110). For example, the driver 1105 can drive the emitter 1104 with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver 1105 can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter 1104. In some embodiments, the driver 1105 is capable of driving the emitter 1104 to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount 1106 provides a support structure in certain embodiments for aligning the top-emitting LEDs 1102 and the side-emitting LEDs 1104 so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount 1106 is also constructed of aluminum nitride (AlN) or beryllium oxide (BEO) for heat dissipation, although other materials or combinations of materials suitable for the submount 1106 can be used.

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter 104 may be driven in a progressive fashion to minimize noise and increase SNR of sensor 101. For example, emitter 104 may be driven based on a progression of power/current delivered to LEDs 1102 and 1104.

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In some embodiments, emitter 104 may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 may emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter 104 may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. 11B shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs 1102. FIG. 11B also shows that emitter 104 may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs 1104. Emitter 104 may be progressively driven at higher power/current. This progression may allow driver circuit 105 to stabilize in its operations, and thus, provide a more stable current/power to LEDs 1102 and 1104.

For example, as shown in FIG. 11B, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs 1102 may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs 1104 (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit 1105 to stabilize after operating at higher current/power.

As shown in FIG. 11B, top emitting LEDs 1102 may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs 1102 may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs 502 for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter 104.

Subsequently, side emitting LEDs 1104 may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site 102 to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment, the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the current needed to drive side emitting LEDs 1104. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter 104.

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As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit 1105 to stabilize its power delivery to LEDs 1102 and 1104. Driver circuit 1105 may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a variable waiting period to allow for stabilization of driver circuit 1105. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system 100. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit 1105 may monitor temperatures of the LEDs 1102 and 1104 using the thermistor 1120 and adjust the output of LEDs 1102 and 1104 accordingly. Such a temperature may be to help sensor 101 correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter 104 can include components mounted on a substrate 1108 and on submount 1106. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108. Side emitting LEDs 1104 may be mounted on submount 1106. As noted, side-emitting LEDs 1104 may be included in emitter 104 for emitting near infrared light.

As also shown, the sensor of FIG. 11C may include a thermistor 1120. As noted, the thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter 104 may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter 104 that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter 104 can include components mounted on the substrate 1108. In particular, top-emitting LEDs 1102 for emitting red and/or infrared light may be mounted on substrate 1108.

As also shown, the emitter of FIG. 11D may include a thermistor 1120. The thermistor 1120 can be provided to compensate for temperature variations. The thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 due to heating.

FIG. 12A illustrates a detector submount 1200 having photodiode detectors that are arranged in a grid pattern on the detector submount 1200 to capture light at different quadrants from a measurement site. One detector submount 1200 can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount 1200. The detector submount 1200 can also be used with the partially cylindrical protrusion 605 described above with respect to FIG. 6.

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The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount 1200 to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors 106 and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site 102). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. 12B through 12D illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors 106. As shown, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount 1200 to capture light at different quadrants from measurement site 102.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors 106 may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors 106 may be employed by embodiments of the present disclosure.

For example, as shown in FIG. 12B, detectors 106 may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount 1200. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

In FIG. 12C, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount 1200, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances $D1 > D2 > D3$). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. 12D, a different substantially grid pattern on submount 1200 of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. 12E through 12H illustrate several embodiments of photodiodes that may be used in detectors 106. As shown in these figures, a photodiode 1202 of detector 106 may comprise a plurality of active areas 1204. These active areas 204 may be coupled together via a common cathode 1206 or anode 1208 in order to provide a larger effective detection area.

In particular, as shown in FIG. 12E, photodiode 1202 may comprise two (2) active areas 1204a and 1204b. In FIG. 12F, photodiode 1202 may comprise four (4) active areas 1204c-f. In FIG. 12G, photodiode 1202 may comprise three (3)

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active areas 1204g-i. In FIG. 12H, photodiode 1202 may comprise nine (9) active areas 1204j-r. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode 1202.

FIG. 13 illustrates an example multi-stream process 1300. The multi-stream process 1300 can be implemented by the data collection system 100 and/or by any of the sensors described above. As shown, a control signal from a signal processor 1310 controls a driver 1305. In response, an emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302. As described above, in some embodiments, the pulse sequence 1303 is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence 1303 can be greater (or smaller).

In response to the pulse sequence 1300, detectors 1 to n (n being an integer) in a detector 1306 capture optical radiation from the measurement site 1302 and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter 1304. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface 1308 can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor 1310. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter 1304.

The signal processor 1310 can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor 1310 can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

Absorbance $A = m \cdot b \cdot c$, where:

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of $M^{-1} \text{ cm}^{-1}$);

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

In spectroscopy, instruments attempt to obtain the analyte concentration (c) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$T = I/I_0$, where:

I is the light intensity measured by the instrument from the measurement site; and

I_0 is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A = -\log T$$

Therefore, substituting equations from above:

$$A = -\log (I/I_0)$$

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In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I/I_0)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_0), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude than what is achievable by currently available technology.

In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T = e^{-m \cdot b \cdot c}$$

In terms of light intensity, this equation can also be rewritten as:

$$I/I_0 = e^{-m \cdot b \cdot c}$$

Or, at a detector, the measured light (I) can be expressed as:

$$I = I_0 \cdot e^{-m \cdot b \cdot c}$$

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $I_1 \dots I_n$ streams of measurements. Assuming each of these detectors have their

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own path lengths, $b_1 \dots b_n$, from the light source, the measured light intensities can be expressed as:

$$I_n = I_o * e^{-m * b_n * c}$$

The measured light intensities at any two different detectors can be referenced to each other. For example:

$$I_1/I_n = (I_o * e^{-m * b_1 * c}) / (I_o * e^{-m * b_n * c})$$

As can be seen, the terms, I_o , cancel out and, based on exponent algebra, the equation can be rewritten as:

$$I_1/I_n = e^{-m(b_1 - b_n)c}$$

From this equation, the analyte concentration (c) can now be derived from bulk signals $I_1 \dots I_n$ and knowing the respective mean path lengths b_1 and b_n . This scheme also allows for the cancelling out of I_o , and thus, noise generated by the emitter 130a can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) 1302. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. 14A illustrates an embodiment of a detector submount 1400a positioned beneath the partially cylindrical protrusion 605 of FIG. 6 (or alternatively, the protrusion 605b). The detector submount 1400a includes two rows 1408a of detectors 1410a. The partially cylindrical protrusion 605 can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion 605 can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion 605, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

Applying the partially cylindrical protrusion 605 to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion 605 (see FIG. 14B). This is the example situation illustrated in FIG. 14—two rows 1408a of detectors 1410a are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion 605 can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the

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detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion 605 (or alternatively, the protrusion 605b) that illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors. The protrusion 605 is placed above a detector submount 1400b having one or more detectors 1410b disposed thereon. The submount 1400b can include any number of rows of detectors 1410, although one row is shown.

Light, represented by rays 1420, is emitted from the emitters onto the protrusion 605. These light rays 1420 can be attenuated by body tissue (not shown). When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion 605. The refraction causes the rays 1422 to be focused or substantially focused on the one or more detectors 1410b. Since the light is focused on a smaller area, a sensor including the protrusion 605 can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. 14C illustrates another embodiment of a detector submount 1400c, which can be disposed under the protrusion 605b (or alternatively, the protrusion 605). The detector submount 1400c includes a single row 1408c of detectors 1410c. The detectors are electrically connected to conductors 1412c, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount 1400c is shown positioned under the protrusion 605b in a detector subassembly 1450 illustrated in FIG. 14D. A top-down view of the detector subassembly 1450 is also shown in FIG. 14E. In the detector subassembly 1450, a cylindrical housing 1430 is disposed on the submount 1400c. The cylindrical housing 1430 includes a transparent cover 1432, upon which the protrusion 605b is disposed. Thus, as shown in FIG. 14D, a gap 1434 exists between the detectors 1410c and the protrusion 605b. The height of this gap 1434 can be chosen to increase or maximize the amount of light that impinges on the detectors 1410c.

The cylindrical housing 1430 can be made of metal, plastic, or another suitable material. The transparent cover 1432 can be fabricated from glass or plastic, among other materials. The cylindrical housing 1430 can be attached to the submount 1400c at the same time or substantially the same time as the detectors 1410c to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing 1430 in various embodiments.

In certain embodiments, the cylindrical housing 1430 (and transparent cover 1432) forms an airtight or substantially airtight or hermetic seal with the submount 1400c. As a result, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing 1430 can protect the detectors 1410c and conductors 1412c more effectively than currently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing 1430 is at least partially made of metal, the cylindrical housing 1430 can provide noise shielding for the detectors 1410c. For example, the cylindrical housing 1430 can be soldered to a ground connection or ground plane on the submount 1400c, which allows the cylindrical housing 1430 to reduce noise. In another embodiment, the transparent cover 1432 can include a conductive material or conductive layer, such as

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conductive glass or plastic. The transparent cover 1432 can include any of the features of the noise shields 790 described above.

The protrusion 605b includes the chamfered edges 607 described above with respect to FIG. 6E. These chamfered edges 607 can allow a patient to more comfortably slide a finger over the protrusion 605b when inserting the finger into the sensor 301f.

FIG. 14F illustrates a portion of the detector shell 306f, which includes the detectors 1410c on the substrate 1400c. The substrate 1400c is enclosed by a shielding enclosure 1490, which can include the features of the shielding enclosures 790a, 790b described above (see also FIG. 17). The shielding enclosure 1490 can be made of metal. The shielding enclosure 1490 includes a window 1492a above the detectors 1410c, which allows light to be transmitted onto the detectors 1410c.

A noise shield 1403 is disposed above the shielding enclosure 1490. The noise shield 1403, in the depicted embodiment, includes a window 1492a corresponding to the window 1492a. Each of the windows 1492a, 1492b can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows 1492a, 1492b may be selected to have different sizes or shapes from each other.

The noise shield 1403 can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield 1403 extends about three-quarters of the length of the detector shell 306f. In other embodiments, the noise shield 1403 could be smaller or larger. The noise shield 1403 could, for instance, merely cover the detectors 1410c, the submount 1400c, or a portion thereof. The noise shield 1403 also includes a stop 1413 for positioning a measurement site within the sensor 301f. Advantageously, in certain embodiments, the noise shield 1403 can reduce noise caused by light piping.

A thermistor 1470 is also shown. The thermistor 1470 is attached to the submount 1400c and protrudes above the noise shield 1403. As described above, the thermistor 1470 can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors 1410c are not enclosed in the cylindrical housing 1430. In an alternative embodiment, the cylindrical housing 1430 encloses the detectors 1410c and is disposed under the noise shield 1403. In another embodiment, the cylindrical housing 1430 encloses the detectors 1410c and the noise shield 1403 is not used. If both the cylindrical housing 1430 and the noise shield 1403 are used, either or both can have noise shielding features.

FIG. 14G illustrates the detector shell 306f of FIG. 14F, with the finger bed 310f disposed thereon. FIG. 14H illustrates the detector shell 306f of FIG. 14G, with the protrusion 605b disposed in the finger bed 310f.

FIG. 14I illustrates a cutaway view of the sensor 301f. Not all features of the sensor 301f are shown, such as the protrusion 605b. Features shown include the emitter and detector shells 304f, 306f, the flaps 307f, the heat sink 350f and fins 351f, the finger bed 310f, and the noise shield 1403.

In addition to these features, emitters 1404 are depicted in the emitter shell 304f. The emitters 1404 are disposed on a submount 1401, which is connected to a circuit board 1419. The emitters 1404 are also enclosed within a cylindrical

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housing 1480. The cylindrical housing 1480 can include all of the features of the cylindrical housing 1430 described above. For example, the cylindrical housing 1480 can be made of metal, can be connected to a ground plane of the submount 1401 to provide noise shielding, and can include a transparent cover 1482.

The cylindrical housing 1480 can also protect the emitters 1404 from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing 1480 can provide a gap between the emitters 1404 and the measurement site (not shown), which can allow light from the emitters 1404 to even out or average out before reaching the measurement site.

The heat sink 350f, in addition to including the fins 351f, includes a protuberance 352f that extends down from the fins 351f and contacts the submount 1401. The protuberance 352f can be connected to the submount 1401, for example, with thermal paste or the like. The protuberance 352f can sink heat from the emitters 1404 and dissipate the heat via the fins 351f.

FIGS. 15A and 15B illustrate embodiments of sensor portions 1500A, 1500B that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions 1500A, 1500B shown include LED emitters 1504; however, for ease of illustration, the detectors have been omitted. The sensor portions 1500A, 1500B shown can be included, for example, in any of the emitter shells described above.

The LEDs 1504 of the sensor portions 1500A, 1500B are connected to a substrate or submount 1502. The submount 1502 can be used in place of any of the submounts described above. The submount 1502 can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable 1512 is attached to the submount 1502 and includes electrical wiring 1514, such as twisted wires and the like, for communicating with the LEDs 1504. The cable 1512 can correspond to the cables 212 described above.

Although not shown, the cable 1512 can also include electrical connections to a detector. Only a portion of the cable 1512 is shown for clarity. The depicted embodiment of the cable 1512 includes an outer jacket 1510 and a conductive shield 1506 disposed within the outer jacket 1510. The conductive shield 1506 can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield 1506 or a portion of the conductive shield 1506 can be electrically connected to the submount 1502 and can reduce noise in the signal generated by the sensor 1500A, 1500B by reducing RF coupling with the wires 1514. In alternative embodiments, the cable 1512 does not have a conductive shield. For example, the cable 1512 could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. 15A, in certain embodiments, the conductive shield 1506 can act as a heat sink for the LEDs 1504 by absorbing thermal energy from the LEDs 1504 and/or the submount 1502. An optional heat insulator 1520 in communication with the submount 1502 can also assist with directing heat toward the conductive shield 1506. The heat insulator 1520 can be made of plastic or another suitable material. Advantageously, using the conductive shield 1506 in the cable 1512 as a heat sink can, in certain embodiments, reduce cost for the sensor.

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Referring to FIG. 15B, the conductive shield 1506 can be attached to both the submount 1502 and to a heat sink layer 1530 sandwiched between the submount 1502 and the optional insulator 1520. Together, the heat sink layer 1530 and the conductive shield 1506 in the cable 1512 can absorb at least part of the thermal energy from the LEDs and/or the submount 1502.

FIGS. 15C and 15D illustrate implementations of a sensor portion 1500C that includes the heat sink features of the sensor portion 1500A described above with respect to FIG. 15A. The sensor portion 1500C includes the features of the sensor portion 1500A, except that the optional insulator 1520 is not shown. FIG. 15D is a side cutaway view of the sensor portion 1500C that shows the emitters 1504.

The cable 1512 includes the outer jacket 1510 and the conductive shield 1506. The conductive shield 1506 is soldered to the submount 1502, and the solder joint 1561 is shown. In some embodiments, a larger solder joint 1561 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, a cylindrical housing 1580, corresponding to the cylindrical housing 1480 of FIG. 14I, is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15E and 15F illustrate implementations of a sensor portion 1500E that includes the heat sink features of the sensor portion 1500B described above with respect to FIG. 15B. The sensor portion 1500E includes the heat sink layer 1530. The heat sink layer 1530 can be a metal plate, such as a copper plate or the like. The optional insulator 1520 is not shown. FIG. 15F is a side cutaway view of the sensor portion 1500E that shows the emitters 1504.

In the depicted embodiment, the conductive shield 1506 of the cable 1512 is soldered to the heat sink layer 1530 instead of the submount 1502. The solder joint 1565 is shown. In some embodiments, a larger solder joint 1565 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, the cylindrical housing 1580 is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. 1 through 15F. Referring to FIG. 15G, the circuit board 1519 includes a female connector 1575 that mates with a male connector 1577 connected to a daughter board 1587. The daughter board 1587 includes connections to the electrical wiring 1514 of the cable 1512. The connected boards 1519, 1587 are shown in FIG. 15H. Also shown is a hole 1573 that can receive the cylindrical housing 1580 described above.

Advantageously, in certain embodiments, using a daughter board 1587 to connect to the circuit board 1519 can enable connections to be made more easily to the circuit board 1519. In addition, using separate boards can be easier to manufacture than a single circuit board 1519 with all connections soldered to the circuit board 1519.

FIG. 15I illustrates an exemplary architecture for front-end interface 108 as a transimpedance-based front-end. As noted, front-end interfaces 108 provide an interface that adapts the output of detectors 106 into a form that can be handled by signal processor 110. As shown in this figure, sensor 101 and front-end interfaces 108 may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor

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101 and front end interfaces 108 may comprise multiple components or circuits that are coupled together.

Front-end interfaces 108 may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors 106. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter 900 may be integrated with the transimpedance-based front-end in sensor 101.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector 106, the applicants developed a noise model to assist in configuring front-end 108. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise} = \sqrt{aR + bR^2}, \text{ where:}$$

aR is characteristic of the impedance of the transimpedance amplifier; and

bR² is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector 106.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in FIG. 12A) may each comprise four photodiodes. In some embodiments, each detector of four photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. 15J.

Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the

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transimpedance amplifiers in this setting may also be set according to the model shown in FIG. 15J.

As yet another alternative, as noted above with respect to FIGS. 12E through 12H, the photodiodes in detectors 106 may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. 15J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary "4 PD per stream" sensor 1502 is shown where detector 106 comprises four photodiodes 1502. The photodiodes 1502 are coupled to a single transimpedance amplifier 1504 to produce an output stream 1506. In this example, the transimpedance amplifier comprises 10 M Ω resistors 1508 and 1510. Thus, output stream 1506 is produced from the four photodiodes (PD) 1502. As shown in the graph of FIG. 15J, the model indicates that resistance values of about 10 M Ω may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary "1 PD per stream" sensor 1512 is also shown in FIG. 15J. In particular, sensor 1512 may comprise a plurality of detectors 106 that each comprises a single photodiode 1514. In addition, as shown for this example configuration, each of photodiodes 1514 may be coupled to respective transimpedance amplifiers 1516, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 M Ω resistors 1518. As also shown in the graph of FIG. 15J, the model illustrates that resistance values of 40 M Ω for resistors 1518 may serve as an alternative to the 4 photodiode per stream architecture of sensor 1502 described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor 1512 may provide enhanced performance because each of transimpedance amplifiers 1516 can be tuned or optimized to its respective photodiodes 1518. In some embodiments, an averaging component 1520 may also be used to help cancel or reduce noise across photodiodes 1518.

For purposes of illustration, FIG. 15K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor 1522 may comprise a "4 PD per stream" architecture on a submount 700 in which each detector 106 comprises four (4) photodiodes 1524. As shown for sensor 1522, the output of each set of four photodiodes 1524 is then aggregated into a single transimpedance amplifier 1526 to produce a signal.

As another example, a sensor 1528 may comprise a "1 PD per stream" architecture on submount 700 in which each detector 106 comprises four (4) photodiodes 1530. In sensor 1528, each individual photodiode 1530 is coupled to a respective transimpedance amplifier 1532. The output of the amplifiers 1532 may then be aggregated into averaging circuit 1520 to produce a signal.

As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor 1534 illustrates an exemplary "4 PD per stream" sensor in which the detectors 106 comprise photo-

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diodes 1536 arranged in a linear fashion. Likewise, sensor 1538 illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes 1540 arranged in a linear fashion.

Alternatively, sensor 1542 illustrates an exemplary "4 PD per stream" sensor in which the detectors 106 comprise photodiodes 1544 arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor 1546 illustrates an exemplary "1 PD per stream" sensor in which the detectors comprise photodiodes 1548 also arranged in a zig-zag pattern.

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces 108 may be implemented using switched capacitor circuits and any number of front-end interfaces 108 may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface 1000 and signal processor 110. Switched capacitor circuits may be useful in system 100 for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces 108 may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces 108 may require less computational power by signal processor 110 to perform the same amount of decimation to obtain the same SNR.

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors 1600. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors 1600 shown. For instance, the sensors 1600 can be used as the sensors 101 in the system 100 described above with respect to FIG. 1. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors 1600 include an adult/pediatric sensor 1610 for finger placement and a disposable infant/neonate sensor 1602 configured for toe, foot or hand placement. Each sensor 1600 has a tape end 1610 and an opposite connector end 1620 electrically and mechanically interconnected via a flexible coupling 1630. The tape end 1610 attaches an emitter and detector to a tissue site. Although not shown, the tape end 1610 can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

The sensor signal is communicated via the flexible coupling 1630 to the connector end 1620. The connector end 1620 can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. 2A through 2D. Alternatively, the connector end 1620 can mate directly with the monitor.

FIG. 17 illustrates an exploded view of certain of the components of the sensor 301f described above. A heat sink 1751 and a cable 1781 attach to an emitter shell 1704. The emitter shell attaches to a flap housing 1707. The flap housing 1707 includes a receptacle 1709 to receive a cylin-

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drical housing 1480/1580 (not shown) attached to an emitter submount 1702, which is attached to a circuit board 1719.

A spring 1787 attaches to a detector shell 1706 via pins 1783, 1785, which hold the emitter and detector shells 1704, 1706 together. A support structure 1791 attaches to the detector shell 1706, which provides support for a shielding enclosure 1790. A noise shield 1713 attaches to the shielding enclosure 1790. A detector submount 1700 is disposed inside the shielding enclosure 1790. A finger bed 1710 provides a surface for placement of the patient's finger. Finger bed 1710 may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion 1705 may also be disposed in the finger bed 1710. As shown, finger bed 1710 attaches to the noise shield 1703. The noise shield 1703 may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield 1703 may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield 1703 may also comprise a thermistor 1712. The thermistor 1712 may be helpful in measuring the temperature of a patient's finger. For example, the thermistor 1712 may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor 1712 may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover 1706 attaches to the pins 1783, 1785. Although not shown, a flex circuit can also be provided that connects the circuit board 1719 with the submount 1700 (or a circuit board to which the submount 1700 is connected). A flex circuit protector 1760 may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector 1760 may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector 1760 may be constructed from well known materials, such as a plastic or rubber materials.

FIG. 18 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor 101 were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

FIG. 19 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor 101 were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

FIGS. 20 through 22 shows other results that can be obtained by an embodiment of system 100. In FIG. 20, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with

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an embodiment of system 100 that comprised four LEDs and four independent detector streams. As shown, the system 100 obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. 21, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106. As shown, the system 100 was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. 22 relate to total hemoglobin testing with an exemplary sensor 101 of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector channels from detectors 106. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

What is claimed is:

1. A user-worn device configured to non-invasively determine measurements of physiological parameter of a user, the user-worn device comprising:

a plurality of light emitting diodes (LEDs);

four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user; a protrusion comprising a convex surface and a plurality of openings extending through the protrusion, the openings arranged over the photodiodes and configured to allow light to pass through the protrusion to the photodiodes; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

2. The user-worn device of claim 1, wherein the one or more processors are further configured to process the one or

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more signals to determine a bulk measurement indicating a positioning of the user-worn device.

3. The user-worn device of claim 1 further comprising optically transparent glass windows, each window extending across a different one of the openings.

4. The user-worn device of claim 1, wherein the plurality of LEDs and the photodiodes are positioned on a same side of tissue of the user.

5. The user-worn device of claim 1, wherein the protrusion further comprises an opaque material, and wherein the one or more signals are substantially free of noise caused by light piping.

6. A user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes arranged on a surface and configured to receive light after at least a portion of the light has been attenuated by tissue of a user;

a protrusion arranged above the surface, the protrusion comprising a convex surface including windows, the windows extending across the four photodiodes, wherein light passes through the protrusion to the four photodiodes via at least the windows;

a thermistor configured to provide a temperature signal; and

one or more processors configured to:

receive one or more signals from at least one of the photodiodes;

receive the temperature signal; and

adjust operation of the user-worn device responsive to the temperature signal.

7. The user-worn device of claim 6, wherein the protrusion further comprises an opaque material, the opaque material extending from the convex surface of the protrusion to an interior surface of the protrusion opposite the convex surface.

8. A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:

a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;

a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes;

a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;

a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;

a separate optically transparent window extending across each of the openings;

one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;

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a housing; and

a strap configured to position the housing proximate tissue of the user when the device is worn.

9. The user-worn device of claim 8 further comprising a network interface configured to wirelessly communicate the measurements of the physiological parameter to at least one of a mobile phone or a computer network.

10. The user-worn device of claim 9 further comprising a user interface including a touch-screen display configured to display indicia responsive to the measurements of the physiological parameter.

11. The user-worn device of claim 10, wherein an orientation of the user interface is configurable responsive to a user input.

12. The user-worn device of claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.

13. The user-worn device of claim 8 further comprising a storage device configured to at least temporarily store at least the measurements of the physiological parameter.

14. The user-worn device of claim 8, wherein the physiological parameter comprises pulse rate.

15. The user-worn device of claim 8 further comprising a thermistor.

16. The user-worn device of claim 8, wherein the openings are configured to prevent light piping.

17. The user-worn device of claim 8, wherein the housing hermetically seals at least a portion of an interior of the user-worn device.

18. The user-worn device of claim 8, wherein the windows comprise a conductive material.

19. The user-worn device of claim 8, wherein the windows are arranged on the protrusion configured to be in contact with tissue of the user.

20. A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:

a plurality of light emitting diodes (LEDs);

at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;

a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and

one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

21. The user-worn device of claim 20, wherein the one or more processors are further configured to process the one or more signals to determine a bulk measurement indicating a positioning of the user-worn device.

22. The user-worn device of claim 20, wherein the plurality of LEDs and the photodiodes are positioned on a same side of the user's tissue.

23. The user-worn device of claim 20, wherein the one or more signals are substantially free of noise caused by light piping.

24. The user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping.

25. The user-worn device of claim 20, further comprising gaps between the photodiodes and the windows.

26. The user-worn device of claim 20, wherein the photodiodes are arranged in a quadrant configuration.

27. The user-worn device of claim 26, further comprising opaque walls surrounding the photodiodes.

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28. The user-worn device of claim 27, wherein the walls are configured to reduce mixing of light from distinct quadrants of the tissue.

29. The user-worn device of claim 20, wherein the protrusion further comprises one or more extensions. 5

30. The user-worn device of claim 20, wherein the protrusion further comprises one or more chamfered edges.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,945,648 B2
 APPLICATION NO. : 17/031316
 DATED : March 16, 2021
 INVENTOR(S) : Jeroen Poeze

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (60), Page 2, Column 1 at Line 10, Related U.S. Application Data, Change "which is a division" to --which is a continuation--.

Item (60), Page 2, Column 1 at Line 22, Related U.S. Application Data, Change "and a continuation-in-part" to --said application No. 12/829,352 is a continuation-in-part--.

In the Specification

In Column 35 at Line 8 (approx.), Change " $l_1/l_n = (l_o * e^{-mb_1c})/(l_{oIL} * e^{-mb_nc})$," to
 -- " $l_1/l_n = (l_o * e^{-mb_1c})/(l_o * e^{-mb_nc})$ --.

In Column 38 at Line 22, Change "15008" to --1500B--.

In Column 38 at Line 53, Change "15008" to --1500B--.

Signed and Sealed this
 Twentieth Day of April, 2021



Drew Hirshfeld
 Performing the Functions and Duties of the
 Under Secretary of Commerce for Intellectual Property and
 Director of the United States Patent and Trademark Office



UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

February 5, 2024

Hon. Jarrett B. Perlow, Clerk
U.S. Court of Appeals for the Federal Circuit
Office of the Clerk
717 Madison Place, NW
Washington, DC 20439

RE: 24-1285 – *Apple Inc. v. International Trade Commission*

Dear Mr. Perlow:

Pursuant to Rule 17 of the rules of this Court, and Rule 17(b) of the Federal Rules of Appellate Procedure, we hereby transmit a certified list of the agency record in **Investigation No. 337-TA-1276 – *Certain Light-Based Physiological Measurement Devices and Components Thereof***.

This list is filed in connection with the above-referenced appeal.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton
Secretary to the Commission

Enclosure:
Certified List

INVESTIGATION REPORT
Investigation No. 337-TA-1276**Date/Time: 02/05/2024, 12:00 PM****Page 1 of 60****Total Records = 656****Investigation Report**

Print Date/Time: 02/05/2024

Investigation Number: 337-1276 Violation Total Records: 656

Official Received Date	Doc ID - Sec Level	Investigation Information (Document Type, Document Title, Filed By, Firm, On Behalf Of)
06/30/2021	(745713 - Public)	Complaint, Public Complaint and Exhibits, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/30/2021	(745719 - Confidential)	Complaint, Confidential Exhibits to the Public Complaint, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/30/2021	(745736 - Public)	Complaint, Appendices A-F, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/30/2021	(745739 - Public)	Complaint, Appendices F-H, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/30/2021	(745772 - Public)	Notice, Receipt of Complaint; Solicitation of Comments Relating to the Public Interest, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
07/07/2021	(746186 - Public)	Complaint, Amendment to the Public Complaint, with Amended Exhibit 2 and Appendix C, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/12/2021	(746514 - Confidential)	Complaint, Confidential Amendment to the Public Complaint and Exhibits, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/14/2021	(746847 - Public)	Comments/Response to Comments, Public Interest Statement of Proposed Respondent Apple Inc., filed by Mark Selwyn of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/15/2021	(746934 - Public)	Notice, 86 FR 35533 F.R. Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
07/16/2021	(747137 - Public)	Notice, Receipt of Amended Complaint; Solicitation of Comments Relating to the Public Interest, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
07/19/2021	(747240 - Public)	Complaint, Supplement to the Amended Public Complaint and Exhibits, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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07/19/2021	(747244 - Confidential)	Complaint, Supplement to the Confidential Amended Complaint and Exhibits, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/19/2021	(747251 - Confidential)	Comments/Response to Comments, Complainants' Reply to Public Interest Statement of Proposed Respondent Apple, Inc., filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/20/2021	(747380 - Public)	Comments/Response to Comments, Public Cover Letter, Request for Confidential Treatment, and Reply to Public Interest Statement of Proposed Respondent Apple, Inc., filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/23/2021	(747675 - Public)	Notice, 86 FR 38764 F.R. Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
07/30/2021	(748374 - Confidential)	Comments/Response to Comments, Public Interest Statement of Proposed Respondent Apple Inc., filed by Mark Selwyn of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/02/2021	(748490 - Public)	Comments/Response to Comments, Public Interest Statement of Proposed Respondent Apple, Inc., filed by Mark Selwyn of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/03/2021	(748598 - Public)	Correspondence - USITC, Postponement Letter to Jonathan E. Bachand of Knobbe, Martens, Olson, & Bear, LLP, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
08/04/2021	(748672 - Confidential)	Comments/Response to Comments, Complainants' Reply to Apple's Second Public Interest Statement, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/04/2021	(748674 - Public)	Comments/Response to Comments, Complainants' Reply to Apple's Second Public Interest Statement, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/13/2021	(749538 - Public)	Notice, Institution of Investigation, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
08/13/2021	(749559 - Public)	Notice, Assignment of CALJ Bullock, filed by Charles E. Bullock of USITC, on behalf of Chief Administrative Law Judge
08/18/2021	(749846 - Public)	Correspondence, Proof of Service of Complaint on Respondent Apple Inc., filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/18/2021	(749877 - Public)	Order, 1 Protective Order, filed by Charles E. Bullock of USITC, on behalf of Chief Administrative Law Judge

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08/18/2021	(749878 - Public)	Order, 2 Notice of Ground Rules; Order Setting Date for Submission of Joint Discovery Statement, filed by Charles E. Bullock of USITC, on behalf of Chief Administrative Law Judge
08/19/2021	(749992 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Sarah Frazier, Michael Esch, Nina Garcia, Richard Goldenberg, Derek Gosma, Courtney Merrill, Joseph Mueller, Mark Selwyn, and David Yin, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/19/2021	(749993 - Public)	Notice of Appearance, Notice of Appearance of Wilmer Cutler Pickering Hale and Dorr LLP on Behalf of Apple Inc.; Designation of Sarah Frazier as Lead Counsel, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/20/2021	(749994 - Public)	Request for Confidential Materials, Request for Confidential Materials on Behalf of Apple Inc., filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/20/2021	(749996 - Public)	Notice of Appearance, Notice of Appearance of Knobbe, Martens, Olson & Bear on Behalf of Masimo Corporation and Cercacor Laboratories; Designation of Joseph R. Re as Lead Counsel, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/20/2021	(750000 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Jonathan Bachand, Stephen C. Jensen, Joseph R. Re, Sheila N. Swaroop, William R. Zimmerman, Brian C. Horne, Ted M. Cannon, Alan G. Laquer, Kendall M. Loebbaka, Matthew S. Friedrichs, and Karl W. Kowallis, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/20/2021	(750046 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Thomas Anderson, David Cavanaugh, Jennifer Charlton, Jonathan Cox, Cristina Salcedo, and Jose Valenzuela, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/24/2021	(750207 - Public)	Notice, 86 FR 46275 F.R. Notice of Institution of Investigation, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
08/24/2021	(750230 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Vikram Iyer, Lauren Mandell, Henry Nikogosyan, and David Ross, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/27/2021	(750392 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Labdhi Sheth, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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08/30/2021	(750525 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Cynthia Vreeland, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/31/2021	(750609 - Public)	Discovery Statement, Joint Discovery Statement, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
09/01/2021	(750719 - Public)	Order, 3 Setting Target Date and Deadline for Submission of Proposed Procedural Schedule, filed by Charles E. Bullock of USITC, on behalf of Chief Administrative Law Judge
09/02/2021	(750847 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Douglas B. Wentzel, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/02/2021	(750872 - Confidential)	Motion, 1276-001 7 Respondent's Motion to Preclude Stephen Jensen from Access to Apple's Confidential Business Information under the Protective Order (Order No. 1), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/07/2021	(750986 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Linda Sun, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/07/2021	(751035 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Adam B. Powell, Brian C. Claassen, Cheryl T. Burgess, Daniel P. Hughes, Irfan A. Lateef, Mark D. Kachner, Perry D. Oldham, and Stephen W. Larson, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/07/2021	(751134 - Confidential)	Response/Submission to ALJ Order, Response of Apple Inc. to First Amended Complaint and Notice of Investigation, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/10/2021	(751420 - Public)	Discovery Statement, Discovery Committee Report for August 2021, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
09/13/2021	(751510 - Public)	Motion, 1276-001 7 Respondent's Motion to Preclude Stephen Jensen from Access to Apple's Confidential Business Information under the Protective Order, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/13/2021	(751531 - Public)	Notice, Assignment of ALJ Bhattacharyya, filed by Charles E. Bullock of USITC, on behalf of Chief Administrative Law Judge

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09/13/2021	(751567 - Confidential)	Motion Response/Reply, 1276-001 Complainants' Opposition to Respondent's Motion to Exclude Stephen Jensen from Access to Apple's Confidential Business Information under the Protective Order (Order No. 1), filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/15/2021	(751755 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of H. Mark Lyon, Brian Andrea, and David Brzozowski, filed by Mark Lyon of Gibson, Dunn and Crutcher, on behalf of Apple Inc.
09/16/2021	(751917 - Public)	Notice of Appearance, Supplemental Notice of Appearance; Additional Attorneys from Knobbe, Martens, Olson and Bear on Behalf of Masimo Corporation and Cercacor Laboratories, Inc., filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/16/2021	(751921 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Carol Pitzel Cruz, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/17/2021	(752070 - Public)	Response/Submission to ALJ Order, 3 Joint Proposed Procedural Schedule, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
09/22/2021	(752353 - Public)	Motion Response/Reply, 1276-001 Complainants' Opposition to Respondent's Motion to Exclude Stephen Jensen from Access to Apple's Confidential Business Information under the Protective Order (Order No. 1), filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/22/2021	(752396 - Public)	Order, 4 Issuing Replacement Ground Rules, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/22/2021	(752398 - Public)	ID/RD - Other Than Final on Violation, 5 Initial Determination Extending Target Date by One Month; Rescheduling Hearing Dates; Ordering Submission of Revised Proposed Procedural Schedule, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/22/2021	(752455 - Public)	Motion Response/Reply, 1276-002 Respondent Apple Inc.'s Motion for Leave to File a Reply to Complainants' Opposition to Apple's Motion to Preclude Stephen Jensen from Access to Apple's Confidential Business Information under the Protective Order (Order No. 1), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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09/23/2021	(752521 - Public)	Answer to Complaint, Response of Apple Inc. to First Amended Complaint and Notice of Investigation, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/27/2021	(752732 - Public)	Motion Response/Reply, 1276-002 Complainants' Opposition to Respondent's Motion for Leave to File a Reply to Complainants' Opposition to Apple's Motion to Preclude Stephen Jensen from Access to Apple's Confidential Business Information under the Protective Order (Order No. 1), filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/29/2021	(752893 - Public)	Voting Sheet, OUII-21-046, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
09/29/2021	(752899 - Public)	Voting Sheet, OUII-21-047, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/06/2021	(753565 - Public)	Response/Submission to ALJ Order, 5 Joint Proposed Revised Procedural Schedule, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
10/08/2021	(753817 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Ravi Deol, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
10/12/2021	(754020 - Public)	Notice, 5 Commission Determination Not to Review an Initial Determination Extending the Target Date, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/14/2021	(754138 - Public)	Order, 6 Setting Procedural Schedule, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
10/18/2021	(754397 - Public)	Voting Sheet, GC-21-298, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/18/2021	(754414 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Marko R. Zoretic and Clayton R. Henson, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
10/21/2021	(754767 - Public)	Complaint, Certified Copies of Appendices, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
10/25/2021	(754944 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Vincent Thomas and Bonnie Harvey, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
10/25/2021	(755067 - Public)	Motion, 1276-003 Complainants' Motion to Strike Respondent's Inequitable Conduct Defense, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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10/26/2021	(755104 - Confidential)	Brief Filed With ALJ, Letter Brief on Discovery Dispute regarding Importation and Inventory, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
10/26/2021	(755107 - Confidential)	Brief Filed With ALJ, Apple's Written Explanation of Discovery Dispute, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
10/27/2021	(755205 - Confidential)	Brief Filed With ALJ, Respondent Apple's Response to Statement regarding Importation and Inventory Discovery Dispute, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
10/27/2021	(755206 - Confidential)	Brief Filed With ALJ, Letter Brief in Response to Respondent's Discovery Dispute regarding Request for Production No. 124, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
10/28/2021	(755323 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Vijay K. Madisetti and Daniel M. McGavock, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/02/2021	(755657 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Brittany Amadi, Sydney Donovan, Julius Jefferson, Nora Passamaneck, Michaela Sewall, Thomas Sprankling, and Amy Wigmore, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/02/2021	(755658 - Public)	Other, Respondent Apple Inc.'s Written Explanation of Discovery Dispute, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/02/2021	(755717 - Public)	Brief Filed With ALJ, Letter Brief on Discovery Dispute regarding Importation and Inventory, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/02/2021	(755727 - Public)	Brief Filed With ALJ, Brief in Response to Respondent's Discovery Dispute regarding Request for Production No. 124, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/03/2021	(755848 - Confidential)	Motion, 1276-004 Complainants' Objection to Respondent's Proposed Expert Steve Warren, Ph.D. and Motion for Protective Order to Preclude Access by Steve Warren to Complainants' Confidential Business Information, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/04/2021	(755868 - Public)	Brief Filed With ALJ, Apple's Response to Statement regarding Importation and Inventory Discovery Dispute, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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11/04/2021	(755884 - Confidential)	Transcript, Telephonic Conference (Pages 1-48) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
11/04/2021	(755885 - Public)	Transcript, Telephonic Conference (Pages 1-48) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
11/04/2021	(755943 - Confidential)	Motion Response/Reply, 1276-003 Respondent Apple Inc.'s Opposition to Complainants' Motion to Strike Inequitable Conduct Defense, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/08/2021	(756125 - Confidential)	Motion, 1276-003 Complainants' Reply in Support of Their Motion to Strike Respondent's Inequitable Conduct Defense, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/08/2021	(756139 - Confidential)	Motion, 1276-005 Complainants' Objection to Respondent's Proposed Experts Majid Sarrafzadeh, Ph.D. and Robert Stone, Ph.D., and Motion for Protective Order to Preclude Access by Majid Sarrafzadeh and Robert Stone to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/10/2021	(756348 - Public)	Witness List, Complainants' Identification of Expert Witnesses, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/10/2021	(756357 - Public)	Witness List, Respondent Apple Inc.'s Identification of Expert Witnesses, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/10/2021	(756360 - Public)	Motion, 1276-004 Complainants' Objection to Respondent's Proposed Expert Steve Warren, Ph.D. and Motion for Protective Order to Preclude Access by Steve Warren to Complainants' Confidential Business Information, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/10/2021	(756362 - Public)	Motion, 1276-003 Complainants' Reply in Support of Their Motion to Strike Respondent's Inequitable Conduct Defense, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/12/2021	(756416 - Public)	Motion Response/Reply, 1276-003 Respondent Apple Inc.'s Opposition to Complainants' Motion to Strike Inequitable Conduct Defense, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/15/2021	(756608 - Confidential)	Motion Response/Reply, 1276-004 Respondent Apple Inc.'s Opposition to Complainants' Motion for Protective Order to Preclude Access by Steven Warren, Ph.D. to Complainants' Confidential Business Information, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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11/15/2021	(756621 - Confidential)	Motion, 1276-006 Complainants' Objection to Respondent's Proposed Expert Brian Anthony, Ph.D. and Motion for Protective Order to Preclude Access by Brian Anthony to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/16/2021	(756690 - Public)	Motion, 1276-005 Complainants' Objection to Respondent's Proposed Experts Majid Sarrafzadeh, Ph.D. and Robert Stone, Ph.D., and Motion for Protective Order to Preclude Access by Majid Sarrafzadeh and Robert Stone to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/17/2021	(756828 - Confidential)	Brief Filed With ALJ, Apple's Letter regarding Complainants' Deficient Production of Articles for Inspection, Identity of Individual with Relevant Knowledge, and Internal Business Documents, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/17/2021	(756836 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Daniel C. Kiang, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/18/2021	(756914 - Confidential)	Brief Filed With ALJ, Masimo's Response to Apple's Written Explanation on Deficient Document Production, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/18/2021	(756928 - Confidential)	Order, 1276-001 7 Granting Respondent's Motion to Preclude Stephen Jensen from Access to Confidential Business Information under the Protective Order While Serving on Complainant's Board of Directors, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
11/18/2021	(756931 - Public)	Motion Response/Reply, 1276-004 Reply in Support of Complainants' Objection to Respondent's Proposed Expert Steve Warren, PhD. and Motion for Protective Order to Preclude Access by Steve Warren to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/18/2021	(756950 - Confidential)	Motion Response/Reply, 1276-005 Respondent Apple Inc.'s Opposition to Complainants' Motion for Protective Order to Preclude Access by Majid Sarrafzadeh, Ph.D. and Robert Stone, Ph.D. to Complainants' Confidential Business Information, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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11/19/2021	(756965 - Public)	Motion Response/Reply, 1276-004 Respondent Apple Inc.'s Opposition to Complainants' Motion for Protective Order to Preclude Access by Steven Warren, Ph.D. to Complainants' Confidential Business Information, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/22/2021	(757138 - Public)	Motion, 1276-005 Reply in Support of Complainants' Objection to Respondent's Proposed Experts Majid Sarrafzadeh, Ph.D., and Robert Stone, Ph.D., and Motion for Protective Order to Preclude Access to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/22/2021	(757140 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Andrea L. Cheek, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/22/2021	(757146 - Public)	Motion, 1276-006 Complainants' Objection to Respondent's Proposed Expert Brian Anthony, Ph.D., and Motion for Protective Order to Preclude Access by Brian Anthony to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/23/2021	(757227 - Confidential)	Motion, 1276-007 10 Respondent's Motion to Compel Response to Interrogatory No. 72 Seeking Identity of Individual with Relevant Knowledge, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/26/2021	(757284 - Confidential)	Motion Response/Reply, 1276-005 Respondent Apple Inc.'s Opposition to Complainants' Motion for Protective Order to Preclude Access by Brian Anthony to Complainants' Confidential Business Information, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/26/2021	(757288 - Public)	Motion Response/Reply, 1276-005 Respondent Apple Inc.'s Opposition to Complainants' Motion for Protective Order to Preclude Access by Majid Sarrafzadeh, Ph.D. and Robert Stone, Ph.D. to Complainants' Confidential Business Information, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/26/2021	(757295 - Public)	Brief Filed With ALJ, Masimo's Response to Apple's Written Explanation on Deficient Document Production, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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11/26/2021	(757318 - Public)	Brief Filed With ALJ, Apple's Response to Complainants' Submission regarding Complainants' Deficient Production of Articles for Inspection, Identity of Individuals with Relevant Knowledge, and Internal Business Documents, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/26/2021	(757325 - Confidential)	Transcript, Telephone Conference (Pages 1-47), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
11/29/2021	(757456 - Public)	Motion Response/Reply, 1276-006 Reply in Support of Complainants' Objection to Respondent's Proposed Expert Brian Anthony, Ph.D., and Motion for Protective Order to Preclude Access by Brian Anthony to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/30/2021	(757480 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Christian Boettcher, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/01/2021	(757615 - Public)	Motion, 1276-007 10 Respondent's Motion to Compel Response to Interrogatory No. 72 Seeking Identity of Individual with Relevant Knowledge, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/02/2021	(757738 - Public)	Motion Response/Reply, 1276-005 Respondent Apple Inc.'s Opposition to Complainants' Motion for Protective Order to Preclude Access by Brian Anthony Ph.D. to Complainants' Confidential Business Information, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/02/2021	(757739 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Hannah Santasawatkul, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/02/2021	(757745 - Confidential)	Brief Filed With ALJ, Complainants' Letter Brief regarding Discovery Disputes, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/02/2021	(757749 - Confidential)	Brief Filed With ALJ, Apple's Written Submission regarding RFP No. 105, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/03/2021	(757828 - Confidential)	Correspondence, Complainants' Response to Apple's Written Explanation regarding RFP No. 105, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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12/03/2021	(757829 - Confidential)	Brief Filed With ALJ, Respondent Apple Inc.'s Response to Complainants' Written Submission, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/03/2021	(757846 - Confidential)	Motion Response/Reply, 1276-007 Complainants' Opposition to Respondent's Motion to Compel Response to Interrogatory No. 72 Seeking Identity of Individual with Relevant Knowledge, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/07/2021	(758034 - Confidential)	Transcript, Discovery Conference (Pages 1-73), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
12/09/2021	(758255 - Public)	Brief Filed With ALJ, Apple's Written Submission, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/10/2021	(758291 - Public)	Brief Filed With ALJ, Complainants' Letter Brief regarding Discovery Disputes, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/10/2021	(758325 - Public)	Brief Filed With ALJ, Apple's Response to Complainants' December 2, 2021 Letter, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/10/2021	(758332 - Public)	Brief Filed With ALJ, Complainants' Response to Apple's Discovery Dispute Letter regarding RFP 105, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/10/2021	(758333 - Public)	Motion, 1276-008 12 Respondent's Motion for Leave to Supplement Identification of Terms for Claim Construction, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/10/2021	(758354 - Public)	Motion, 1276-009 Joint Motion to Designate December 6, 2021 Transcript as Confidential, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
12/13/2021	(758372 - Public)	Motion Response/Reply, 1276-007 Complainants' Opposition to Respondent's Motion to Compel Response to Interrogatory No. 72 Seeking Identity of Individual with Relevant Knowledge, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/13/2021	(758384 - Public)	Order, 1276-009 8 Granting Joint Motion to Designate Transcript as Confidential, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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12/15/2021	(758630 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Ellen Simone and Gordon Miller, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/15/2021	(758681 - Confidential)	Motion, 1276-010 14 Respondent Apple Inc.'s Motion to Compel Production of Documents Referring or Relating to Any Apple Watch Product (Request for Production No. 105), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/16/2021	(758758 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Dennis Davis, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/17/2021	(758777 - Confidential)	Brief Filed With ALJ, Apple Inc.'s Written Submission regarding Complainants' Deficient Responses and Productions Concerning the Purported Patent-Practicing Physical Articles, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/17/2021	(758873 - Public)	Motion Response/Reply, 1276-008 Complainants' Memorandum of Points and Authorities in Opposition to Respondent's Motion for Leave to Supplement Identification of Terms for Claim Construction, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/20/2021	(758890 - Confidential)	Brief Filed With ALJ, Complainants' Response to Apple's Discovery Dispute Letter regarding Deficient Responses and Productions, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/20/2021	(758979 - Confidential)	Motion, 1276-011 Complainants' Motion to Compel Apple to Provide Responses to Request to Request for Production No. 107 and Interrogatory No. 71, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/20/2021	(758983 - Public)	Order, 1276-003 9 Granting Complainants' Motion to Strike Respondent's Inequitable Conduct Defense, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
12/21/2021	(758997 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Tallal Khan Dahar, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/21/2021	(759010 - Confidential)	Transcript, Discovery Conference (Pages 1-46), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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12/22/2021	(759165 - Public)	Brief Filed With ALJ, Complainants' Response to Apple's Discovery Dispute Letter regarding Deficient Responses and Productions, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/23/2021	(759208 - Public)	Motion, 1276-010 14 Respondent Apple Inc.'s Motion to Compel Production of Documents Referring or Relating to any Apple Watch Product (Request for Production No. 105), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/23/2021	(759231 - Public)	Brief Filed With ALJ, Respondent's Submission regarding Complainants' Deficient Responses and Productions Concerning the Purported Patent-Practicing Physical Articles, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/27/2021	(759357 - Confidential)	Motion Response/Reply, 1276-010 Complainants' Memorandum of Points and Authorities in Opposition to Respondent's Motion to Compel Production of Documents Referring or Relating to Any Apple Watch Product (Request for Production No. 105), filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/27/2021	(759278 - Public)	Motion, 1276-011 Complainants' Motion to Compel Apple to Provide Responses to Request to Request for Production No. 107 and Interrogatory No. 71, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/28/2021	(759376 - Confidential)	Motion, 1276-012 31 Respondent Apple Inc.'s Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/29/2021	(759422 - Confidential)	Motion, 1276-013 Joint Motion to Extend Time to Respond to Complainants' Motion to Compel Respondent to Provide Responses to Request for Production No. 107 and Interrogatory No. 71, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
01/04/2022	(759640 - Public)	Order, 1276-013 11 Granting Joint Motion to Extend Time to Respond to Complainants' Motion to Compel, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/04/2022	(759639 - Confidential)	Order, 1276-007 10 Granting Respondent's Motion to Compel Response to Interrogatory No. 72, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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01/05/2022	(759792 - Public)	Motion, 1276-014 13 Joint Motion to Amend the Protective Order to Add Provisions regarding Production and Review of Source Code, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
01/06/2022	(759833 - Public)	Order, 1276-008 12 Granting Respondent's Motion for Leave to Supplement Identification of Terms for Claim Construction, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/06/2022	(759837 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Dustin Stonebrook and Rhonda Norberg, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/10/2022	(760019 - Confidential)	Motion Response/Reply, 1276-012 Respondent Apple Inc.'s Replacement Exhibit FF, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/10/2022	(760044 - Confidential)	Motion Response/Reply, 1276-012 Complainants' Opposition to Apple Inc.'s Motion for Sanctions, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/10/2022	(760057 - Confidential)	Motion, 1276-015 20 Respondent Apple Inc.'s Motion to Compel Production of All Photographs and Videos of Physical Items Made Available by Complainants for Inspection in This Investigation (Request for Production No. 177), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/10/2022	(760064 - Public)	Motion, 1276-004 Contingent Notice of Withdrawal of Complainants' Objections and Motions for Protective Orders to Preclude Access by Respondent's Proposed Experts Steve Warren; Majid Sarrafzadeh, PhD; Robert Stone, PhD; and Brian Anthony, to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/10/2022	(760100 - Public)	Order, 1276-014 13 Granting Joint Motion to Amend the Protective Order to Add Provisions regarding Production and Review of Source Code, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/11/2022	(760270 - Public)	Motion, 1276-012 31 Respondent Apple Inc.'s Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/12/2022	(760308 - Public)	Order, 1276-001 7 Granting Respondent's Motion to Preclude Stephen Jensen from Access to Confidential Business Information under the Protective Order While Serving on Complainant's Board of Directors, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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01/12/2022	(760310 - Public)	Order, 1276-007 10 Granting Respondent's Motion to Compel Response to Interrogatory No. 72, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/12/2022	(760346 - Confidential)	Motion Response/Reply, 1276-012 Respondent Apple Inc.'s Reply in Support of Its Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/13/2022	(760469 - Public)	Other, Joint Proposed Claim Construction Chart, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
01/14/2022	(760547 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Benjamin Goldberg, Majid Sarrafzadeh, Robert Stone, and Steven Warren, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/14/2022	(760563 - Public)	Motion, 1276-015 20 Respondent Apple Inc.'s Motion to Compel Production of All Photographs and Videos of Physical Items Made Available by Complainants for Inspection in This Investigation (Request for Production No. 177), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/18/2022	(760703 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Brian Anthony, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/18/2022	(760808 - Confidential)	Motion, 1276-016 19 Complainants' Motion to Compel Apple to Respond to Requests regarding Apple's Unreleased Products and Components Thereof with Light-Based Pulse Oximetry Functionality (Request for Admission Nos. 13-29, 37-40; Interrogatory Nos. 7, 65-68; Request for Production Nos. 145-149, 155-157), filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/19/2022	(760884 - Confidential)	Order, 1276-010 14 Granting-in-Part and Denying-in-Part Respondent's Motion to Compel Production of Documents Referring or Relating to Any Apple Watch Product, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/19/2022	(760898 - Public)	Motion, 1276-012 Respondent Apple Inc.'s Reply in Support of Its Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/19/2022	(760900 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of John Muskivitch, Vincent Thomas, and Bonnie Harvey, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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01/19/2022	(760925 - Confidential)	Brief Filed With ALJ, Apple Letter Brief regarding Complainants' Deficient Domestic Industry Responses, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/19/2022	(760932 - Confidential)	Brief Filed With ALJ, Complainants' Written Explanation regarding Discovery Dispute, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/19/2022	(760953 - Confidential)	Motion Response/Reply, 1276-015 Complainants' Memorandum of Points and Authorities in Opposition to Respondent's Motion to Compel Production of All Photographs and Videos of Physical Items Made Available by Complainants for Inspection in This Investigation (Request for Production No.177), filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/20/2022	(760972 - Public)	Motion Response/Reply, 1276-012 Complainants' Opposition to Apple Inc.'s Motion for Sanctions, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/20/2022	(761003 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Alison Burton, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/20/2022	(761004 - Public)	PO Subscription, Withdrawal of the Agreement to Be Bound by the Protective Order of John Muskivitch, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/20/2022	(761035 - Confidential)	Brief Filed With ALJ, Complainants' Response to Apple's January 19, 2022 Discovery Dispute Letter, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/20/2022	(761042 - Confidential)	Brief Filed With ALJ, Letter Brief regarding Discovery Teleconference, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/21/2022	(761070 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Gail D. Baura, Reginald James Duckworth, Jack Goldberg, James F. Shanley, and Vijay K. Madisetti, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/21/2022	(761123 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of David Chroniger, Dylan Keisler, and Nancy Bendish, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/24/2022	(761200 - Confidential)	Transcript, Discovery Conference (Pages 1-62) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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01/24/2022	(761201 - Public)	Transcript, Discovery Conference (Pages 1-62) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/27/2022	(761559 - Public)	Motion, 1276-016 Complainants' Motion to Compel Apple to Respond to Requests regarding Apple's Unreleased Products and Components Thereof with Light-Based Pulse Oximetry Functionality (Request for Admission Nos. 13-29, 37-40; Interrogatory Nos. 7, 65-68; Request for Production Nos. 145-149, 155-157), filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/27/2022	(761560 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Timothy Trost, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/27/2022	(761605 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Opening Markman Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/27/2022	(761612 - Public)	Brief Filed With ALJ, Complainants' Opening Claim Construction Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/28/2022	(761657 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Laura Donovan, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/28/2022	(761706 - Public)	Notice of Withdrawal of Appearance, Notice of Withdrawal of Appearance of Jennifer Charlton from Wilmer Cutler Pickering Hale and Dorr LLP on Behalf of Apple Inc., filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/28/2022	(761767 - Confidential)	Motion Response/Reply, 1276-016 Respondent Apple Inc.'s Opposition to Complainants' Motion to Compel Responses regarding Unreleased Products (Request for Admission Nos. 13-29, 37-40; Interrogatory Nos. 7, 65-68; and Request for Production Nos. 145-149, 155-157), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/31/2022	(761872 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Nicholas P. Godici, Thomas H. Lupfer, and Robert Louis Stoll, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/31/2022	(761913 - Public)	Brief Filed With ALJ, Complainant's Response to Apple's January 19, 2022 Discovery Dispute Letter, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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01/31/2022	(761968 - Confidential)	Motion, 1276-017 Respondent Apple Inc.'s Motion to Compel Identification of Documents Describing Each Physical Article Complainants Rely on (Interrogatory No. 82), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/01/2022	(762097 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Raina Patel, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/01/2022	(762101 - Public)	Motion Response/Reply, 1276-015 Complainants' Memorandum of Points and Authorities in Opposition to Respondent's Motion to Compel Production of All Photographs and Videos of Physical Items Made Available by Complainants for Inspection in This Investigation, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/01/2022	(762127 - Confidential)	Motion, 1276-018 24 Respondent Apple Inc.'s Motion for Leave to File Amended Response to the First Amended Complaint, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/01/2022	(762143 - Public)	Brief Filed With ALJ, Letter Brief regarding Discovery Teleconference, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/02/2022	(762210 - Public)	Order, 1276-010 14 Granting-in-Part and Denying-in-Part Respondent's Motion to Compel Production of Documents Referring or Relating to Any Apple Watch Product, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
02/03/2022	(762372 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Stacy Rush, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/04/2022	(762458 - Public)	Motion Response/Reply, 1276-011 Notice of Withdrawal of Complainants' Motion to Compel Respondent to Provide Responses to Request for Production No. 107 and Interrogatory No. 71, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/07/2022	(762698 - Public)	Motion, 1276-019 Complainants' Objection to Respondent's Proposed Expert John C. Muskivitch, Ph.D. and Motion for Protective Order to Preclude Access by John Muskovitch to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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02/08/2022	(762761 - Public)	Motion Response/Reply, 1276-016 Respondent Apple Inc.'s Opposition to Complainants' Motion to Compel Responses regarding Unreleased Products (Request for Admission Nos. 13-29, 37-40; Interrogatory Nos. 7, 65-68; and Request for Production Nos. 145-149, 155-157), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/08/2022	(762771 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Nyja Prior, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/08/2022	(762772 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Daniel Holmstock and Eileen Mulvenna, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/08/2022	(762821 - Public)	Motion, 1276-017 21 Respondent Apple Inc.'s Motion to Compel Identification of Documents Describing Each Physical Article Complainants Rely On (Interrogatory No. 82), filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/09/2022	(762886 - Public)	Motion, 1276-018 24 Respondent Apple Inc.'s Motion for Leave to File Amended Response to the First Amended Complaint, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/10/2022	(762982 - Confidential)	Motion Response/Reply, 1276-017 Complainants' Opposition to Respondent's Motion to Compel Identification of Documents Describing Each Physical Article Complainants Rely on (Interrogatory No. 82), filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/10/2022	(762993 - Public)	Brief Filed With ALJ, Complainants' Rebuttal Claim Construction Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/10/2022	(763001 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Rebuttal Markman Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/11/2022	(763017 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Billy Fahnert, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/11/2022	(763048 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Debra Bollman, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/11/2022	(763080 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Theo Green, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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02/11/2022	(763123 - Confidential)	Motion Response/Reply, 1276-018 Complainants' Opposition to Respondent's Motion for Leave to File Amended Response to First Amended Complaint, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/15/2022	(763304 - Public)	Notice of Prior Art, Respondent Apple Inc.'s Notice of Prior Art, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/16/2022	(763313 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Tina Alfaro and Zach Hone, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/16/2022	(763314 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Brian Sparks, Jason Snyder, and Matt Goldstein, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/16/2022	(763315 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Cesar Ballardo, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/16/2022	(763345 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Leslie Todd, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/16/2022	(763351 - Confidential)	Motion Response/Reply, 1276-018 Respondent Apple Inc.'s Reply in Support of Its Motion for Leave to File Amended Response to First Amended Complaint, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/16/2022	(763371 - Confidential)	Motion, 1276-020 22 Respondent Apple Inc.'s Motion to Extend Time to Respond to Complainants' Technical Prong Domestic Industry Contentions for the '501, '502, '648 and '745 Patents, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/16/2022	(763379 - Confidential)	Motion, 1276-021 Respondent Apple Inc.'s Motion for Leave to File a Notice of Supplemental Facts regarding Its Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/17/2022	(763415 - Public)	Motion, 1276-022 15 Complainants' Unopposed Motion for Leave to Take Deposition outside the Close of Fact Discovery, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/17/2022	(763416 - Public)	Motion Response/Reply, 1276-017 Complainants' Opposition to Respondent's Motion to Compel Identification of Documents Describing Each Physical Article Relied On, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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02/17/2022	(763452 - Public)	Order, 1276-022 15 Granting Complainants' Unopposed Motion for Leave to Take Deposition outside the Close of Fact Discovery, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
02/18/2022	(763489 - Public)	Transcript, Tutorial and Markman Hearing (Pages 1-105), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
02/18/2022	(763491 - Public)	Other, Respondent Apple Inc.'s Rebuttal Claim Construction Evidence, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/18/2022	(763555 - Public)	Motion Response/Reply, 1276-019 Complainants' Notice of Withdrawal of Objection to Respondent's Proposed Expert John C. Muskivitch, PhD and Motion for Protective Order to Preclude Access by John Muskivitch to Complainants' Confidential Business Information, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/18/2022	(763577 - Public)	Motion Response/Reply, 1276-018 Complainants' Opposition to Respondent's Motion for Leave to File Amended Response to First Amended Complaint, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/18/2022	(763579 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Henry Marte and Daniel McGavock, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/22/2022	(763605 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Michael Brendan Case, Jaimie Hensley, Catherine Gonzalez, and Austin Olijar, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/22/2022	(763637 - Confidential)	Brief Filed With ALJ, Respondent Apple Inc.'s Brief regarding Discovery Dispute, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/22/2022	(763732 - Confidential)	Correspondence, Complainants' Written Explanation regarding Discovery Disputes regarding Deposition Topics and Interrogatory 104, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/23/2022	(763758 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Jonah Blum, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/23/2022	(763829 - Public)	Motion Response/Reply, 1276-018 Respondent Apple Inc.'s Reply in Support of Its Motion for Leave to File Amended Response to First Amended Complaint, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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02/23/2022	(763831 - Public)	Motion, 1276-020 22 Respondent Apple Inc.'s Motion to Extend Time to Respond to Complainants' Technical Prong Domestic Industry Contentions for the 501, '502, '648 and '745 Patents, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/23/2022	(763833 - Public)	Motion, 1276-021 Respondent Apple Inc.'s Motion for Leave to File a Notice of Supplemental Facts regarding Its Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/24/2022	(763856 - Public)	Other, Updated Joint Proposed Claim Construction Chart, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
02/24/2022	(763857 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of DeShawn White, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/24/2022	(763887 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Rauvin Johl, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/24/2022	(763957 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Inzer Ni, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/24/2022	(763975 - Confidential)	Motion, 1276-023 Complainants' Motion for Leave to File a Notice of Supplemental Facts regarding Motion to Compel, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/25/2022	(764064 - Confidential)	Motion, 1276-024 30 Respondent Apple's Inc.'s Motion for Protective Order to Preclude Depositions of Tim Cook and Jeff Williams, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/25/2022	(764074 - Confidential)	Motion, 1276-025 18 Respondent Apple Inc.'s Motion to Take Certain Third-Party Depositions Out of Time and Request for Shortened Response Time, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/28/2022	(764118 - Public)	Order, 1276-025 16 Shortening Response Time for Respondent's Motion to Take Certain Third-Party Depositions out of Time, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
02/28/2022	(764135 - Confidential)	Motion Response/Reply, 1276-021 Complainants' Opposition to Respondent's Motion for Leave to File a Notice of Supplemental Facts regarding Its Motion for Sanctions, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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02/28/2022	(764137 - Confidential)	Motion Response/Reply, 1276-020 Complainants' Opposition to Respondent's Motion to Extend Time to Respond to Complainants' Technical Prong Domestic Industry Contentions for the '501, '502, '648 and '745 Patents, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/01/2022	(764237 - Public)	Brief Filed With ALJ, Complainants' Written Explanation on Discovery Disputes re Deposition Topics and Interrogatory No. 104, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/01/2022	(764251 - Confidential)	Motion, 1276-026 28 Complainants' Motion to Compel Apple to Provide a Response to Interrogatory 104 and Corporate Testimony (Corporate Deposition Topics (9-10, 19-22, 33-35, 39, and 42) and Request for Shortened Time, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/02/2022	(764305 - Public)	Motion Response/Reply, 1276-026 Respondent Apple Inc.'s Opposition to Complainants' Request for Shortened Response Time, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/02/2022	(764336 - Confidential)	Motion Response/Reply, 1276-025 Complainants' Opposition to Respondent's Motion for Leave to Take Certain Third-Party Depositions out of Time and Request for Shortened Time, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/03/2022	(764442 - Public)	Order, 1276-026 17 Denying Request for Shortened Response Time for Complainants' Motion to Compel, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/03/2022	(764516 - Confidential)	Motion Response/Reply, 1276-020 Respondent Apple Inc. Reply in Support of Its Motion for Leave to File a Notice of Supplemental Facts regarding Its Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/03/2022	(764517 - Confidential)	Order, 1276-025 18 Granting Respondent's Motion to Take Certain Third-Party Depositions out of Time, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/03/2022	(764534 - Confidential)	Motion Response/Reply, 1276-021 Respondent Apple Inc.'s Reply in Support of Its Motion to Extend Time to Respond to Complainants' Technical Prong Domestic Industry Contentions for the '501, '502, '648, '745 Patents, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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03/04/2022	(764634 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Brief regarding Discovery Disputes, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/08/2022	(764815 - Public)	Motion, 1276-024 30 Respondent's Motion for Protective Order to Preclude Depositions of Tim Cook and Jeff Williams, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/09/2022	(764908 - Confidential)	Order, 1276-016 19 Granting-in-Part and Denying-in-Part Complainants' Motion to Compel Apple to Respond to Requests regarding Apple's Unreleased Products and Components Thereof with Light-Based Pulse Oximetry Functionality, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/09/2022	(765006 - Confidential)	Motion Response/Reply, 1276-024 Complainants' Opposition to Respondent's Motion for Protective Order to Preclude Depositions of Tim Cook and Jeff Williams, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/10/2022	(765106 - Public)	Motion Response/Reply, 1276-021 Respondent Apple Inc.'s Reply in Support of Its Motion to Extend Time to Respond to Complainants' Technical Prong Domestic Industry Contentions for the '501, '502, '648, '745 Patents, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/10/2022	(765108 - Public)	Motion Response/Reply, 1276-020 Respondent Apple Inc.'s Reply in Support of Its Motion for Leave to File a Notice of Supplemental Facts regarding Its Motion for Sanctions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/11/2022	(765235 - Confidential)	Motion Response/Reply, 1276-026 Respondent Apple Inc.'s Opposition to Complainants' Motion to Compel a Response to Interrogatory No. 104 and Corporate Testimony for Topic Nos. 9-10, 19-22, 33-35, 39, 42-43, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/15/2022	(765422 - Confidential)	Order, 1276-015 20 Denying Respondent's Motion to Compel Production of Photographs and Videos, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/15/2022	(765424 - Confidential)	Order, 1276-017 21 Denying Respondent's Motion to Compel Identification of Documents, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/15/2022	(765433 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Lori Stokes and Derek Stanley, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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03/16/2022	(765569 - Confidential)	Order, 1276-020 22 Granting Respondent's Motion to Extend Time to Respond to Complainants' Technical Prong Domestic Industry Contentions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/18/2022	(765752 - Confidential)	Motion, 1276-027 Respondent Apple Inc.'s Motion to Strike and Preclude Reliance upon Complainants' Untimely Domestic Industry Contentions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/18/2022	(765814 - Public)	Witness List, Complainants' Tentative Witness List, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/18/2022	(765826 - Public)	Witness List, Respondent Apple Inc.'s Tentative List of Witnesses, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/18/2022	(765827 - Public)	Motion Response/Reply, 1276-026 Respondent Apple Inc.'s Opposition to Complainants' Motion to Compel a Response to Interrogatory No. 104 and Corporate Testimony for Topic Nos. 9-10, 19-22, 33-35, 39, 42-43, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/21/2022	(765894 - Public)	Motion, 1276-028 Joint Motion to Extend Time to Exchange Rebuttal Expert Reports, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
03/21/2022	(765908 - Public)	Order, 1276-028 23 Granting Joint Motion to Extend Time to Exchange Rebuttal Expert Reports, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/21/2022	(765967 - Public)	Motion, 1276-029 Joint Motion for Leave to Take Deposition outside the Close of Expert Discovery and to Extend the Deadline to File a Motion to Compel Expert Discovery, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
03/22/2022	(766084 - Public)	Motion, 1276-030 25 Complainants' Unopposed Motion for Partial Termination by Withdrawal of Certain Claims, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/23/2022	(766180 - Confidential)	Order, 1276-018 24 Granting-in-Part and Denying-in-Part Respondent's Motion for Leave to File Amended Response to the Complaint to Add Affirmative Defenses, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/23/2022	(766184 - Public)	ID/RD - Other Than Final on Violation, 1276-030 25 Initial Determination Granting Complainants' Unopposed Motion for Partial Withdrawal of Certain Claims, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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03/23/2022	(766255 - Public)	Order, 1276-029 26 Granting Joint Motion for Leave to Take Deposition outside the Close of Expert Discovery and to Extend the Deadline to File a Motion to Compel Expert Discovery, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/25/2022	(766613 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Pushkal Mishra, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/25/2022	(766660 - Public)	Motion, 1276-031 Joint Motion for Leave to Submit Supplemental Expert Reports Addressing Investor Testimony, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
03/28/2022	(766756 - Confidential)	Motion Response/Reply, 1276-027 Complainants' Opposition to Respondent Apple Inc.'s Motion to Strike and Preclude Reliance upon Complainants' "Untimely" Domestic Industry Contentions, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
03/28/2022	(766784 - Confidential)	Answer to Complaint, Amended Response of Apple Inc. to First Amended Complaint and Notice of Investigation, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/29/2022	(766836 - Public)	Order, 1276-031 27 Granting Joint Motion for Leave to Submit Supplemental Expert Reports Addressing Inventor Testimony, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/29/2022	(766837 - Confidential)	Order, 1276-026 28 Granting-in-Part and Denying-in-Part Complainants' Motion to Compel Response to Interrogatory and Corporate Deposition Testimony, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/29/2022	(766839 - Public)	Order, 1276-025 18 Granting Respondent's Motion to Take Certain Third-Party Depositions out of Time, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/29/2022	(766840 - Public)	Order, 1276-016 19 Granting-in-Part and Denying-in-Part Complainants' Motion to Compel Apple to Respond to Requests regarding Apple's Unreleased Products and Components Thereof with Light-Based Pulse Oximetry Functionality, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
03/30/2022	(766938 - Public)	Witness List, Respondent Apple Inc.'s Amended Tentative List of Witnesses, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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04/01/2022	(767115 - Confidential)	Motion Response/Reply, 1276-027 Respondent Apple Inc.'s Reply in Support of Its Motion to Strike and Preclude Reliance upon Complainants' Untimely Domestic Industry Contentions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/01/2022	(767116 - Public)	Motion, 1276-032 Joint Motion for Leave to Submit Supplemental Expert Reports of Complainants' Experts Vijay Madisetti and Robert Stoll and to Take a Deposition outside the Close of Expert Discovery, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
04/01/2022	(767159 - Public)	Order, 1276-032 29 Granting Joint Motion for Leave to Submit Supplemental Expert Reports and to Take a Deposition outside the Close of Expert Discovery, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
04/04/2022	(767246 - Public)	Motion, 1276-033 Respondent Apple Inc.'s Unopposed Motion to File Reply in Support of Its Motion to Strike and Preclude Reliance upon Complainants' Untimely Domestic Industry Contentions One Business Day Late, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/04/2022	(767263 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Debra Whitehead, Erin Schuppert, and Jeremy Dineen, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/04/2022	(767307 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Janet McHugh, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
04/05/2022	(767358 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Addison Moyer, Kate Fiebke, and Thomas Lee, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/07/2022	(767569 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Kilian Goltra and Alison Von Dollen, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/08/2022	(767718 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Julia Lunavictoria and Nelly Lin, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/11/2022	(767843 - Public)	Order, 1276-015 20 Denying Respondent's Motion to Compel Production of Photographs and Videos, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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04/11/2022	(767844 - Public)	Order, 1276-017 21 Denying Respondent's Motion to Compel Identification of Documents, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
04/11/2022	(767846 - Public)	Order, 1276-018 24 Granting-in-Part and Denying-in-Part Respondent's Motion for Leave to File Amended Response to the Complaint to Add Affirmative Defenses, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
04/11/2022	(767848 - Public)	Order, 1276-026 28 Granting-in-Part and Denying-in-Part Complainants' Motion to Compel Response to Interrogatory and Corporate Deposition Testimony, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
04/11/2022	(767849 - Public)	Order, 1276-020 22 Granting Respondent's Motion to Extend Time to Respond to Complainants' Technical Prong Domestic Industry Contentions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
04/12/2022	(767970 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of John Parkman, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/12/2022	(767972 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Shaun Kelly and Katie Kreitman, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/12/2022	(768023 - Public)	Notice, 25 Commission Determination Not to Review an Initial Determination Granting Complainants' Motion for Partial Withdrawal of Certain Claims, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
04/13/2022	(768144 - Confidential)	Other, Respondent Apple Inc.'s Stipulation Relating to Next-Generation Apple Watches, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/14/2022	(768230 - Confidential)	Order, 1276-024 30 Granting Respondent's Motion for Protective Order to Preclude Depositions under the "Apex" Doctrine, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
04/14/2022	(768311 - Public)	Voting Sheet, GC-22-115, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
04/18/2022	(768432 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Nathan Hatch, Christian R. Tiedemann, and Lori Goodin, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
04/28/2022	(769432 - Confidential)	Order, 1276-012 31 Denying Respondent's Motion for Sanctions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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04/29/2022	(769464 - Confidential)	Motion, 1276-034 35 Respondent Apple Inc.'s Motion to Strike and Preclude Reliance upon Complainants' Untimely Disclosed Fact Discovery and Expert Opinions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/02/2022	(769565 - Public)	Response/Submission to ALJ Order, 6 Joint Report on Mediation, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
05/02/2022	(769634 - Public)	Transcript, Telephonic Conference (p. 1-18), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
05/05/2022	(769959 - Public)	Order, 1276-024 30 Granting Respondent's Motion for Protective Order to Preclude Depositions under the "Apex" Doctrine, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
05/05/2022	(769965 - Confidential)	Order, 1276-027 32 Granting-in-Part and Denying-in-Part Respondent's Motion to Strike and Preclude Reliance on Complainants' Domestic Industry Contentions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
05/06/2022	(770046 - Confidential)	Other, Respondent Apple Inc.'s Stipulation Relating to Importation and Inventory, filed by Mark Selwyn of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/09/2022	(770202 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Joshua Lerner, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/10/2022	(770365 - Public)	Motion, 1276-034 Respondent Apple Inc.'s Motion to Strike and Preclude Reliance upon Complainants' Untimely Disclosed Fact Discovery and Expert Opinions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/11/2022	(770497 - Confidential)	Motion Response/Reply, 1276-034 Complainants' Opposition to Respondent Apple Inc.'s Motion to Strike and Preclude Reliance upon Complainants' "Untimely Disclosed" Fact Discovery and Expert Opinions, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/13/2022	(770692 - Confidential)	Other, Joint Stipulation of Facts, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
05/13/2022	(770755 - Public)	Pre-Hearing Statement, Complainants' Pre-Hearing Statement, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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05/13/2022	(770783 - Confidential)	Pre-Hearing Statement, Respondent Apple Inc.'s Pre-Hearing Statement, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/13/2022	(770786 - Confidential)	Brief Filed With ALJ, Complainants' Pre-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/13/2022	(770790 - Confidential)	Pre-Hearing Statement, Respondent Apple Inc.'s Pre-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/16/2022	(770853 - Confidential)	Motion Response/Reply, 1276-034 Respondent Apple Inc.'s Reply in Support of Its Motion to Strike and Preclude Reliance upon Complainants' Untimely Disclosed Fact Discovery and Expert Opinions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/16/2022	(770874 - Confidential)	Brief Filed With ALJ, Respondent Apple Inc.'s Corrected Pre-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/17/2022	(770941 - Confidential)	Motion, 1276-035 42 Complainants' Motion in Limine No. 3 to Preclude Apple's Third-Party Witness Robert Rowe from Testifying at the Hearing, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/17/2022	(770951 - Confidential)	Motion, 1276-036 39 Complainants' Motion in Limine No. 1 to Exclude the Kansas State Physical Devices, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/17/2022	(770953 - Confidential)	Motion, 1276-037 38 Respondent Apple's Motion in Limine No. 4 to Preclude Robert Stoll from Presenting Improper Expert Opinion, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/17/2022	(770966 - Confidential)	Motion, 1276-038 41 Respondent Apple Inc.'s Motion in Limine No. 2 to Preclude Evidence or Argument Concerning Alleged Copying by Apple, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/17/2022	(770973 - Confidential)	Motion, 1276-039 Respondent Apple Inc.'s Motion in Limine No. 3 to Exclude Economic Prong Related Evidence Not Provided during Discovery, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/17/2022	(770992 - Confidential)	Exhibit Objections, Complainants' High Priority Objections, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/17/2022	(770997 - Confidential)	Motion, 1276-040 44 Complainants' Motion in Limine No. 4 to Exclude Apple Watch Series 0 as Prior Art to the '745 Patent, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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05/17/2022	(770998 - Confidential)	Motion, 1276-041 40 Complainants' Motion in Limine No. 2 to Preclude Apple from Introducing Evidence regarding Insufficiently Identified Defenses, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/17/2022	(771000 - Confidential)	Motion, 1276-042 37 Respondent Apple Inc.'s Motion in Limine No. 1 to Exclude Evidence and Argument regarding Post-Complaint Developments and Activities, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/17/2022	(771005 - Confidential)	Exhibit Objections, Appendices 1-7 to Complainants' High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/17/2022	(771008 - Confidential)	Exhibit Objections, Respondent Apple Inc.'s High Priority Objections, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/18/2022	(771015 - Confidential)	Exhibit Objections, Appendices 1-7 to Complainants' High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/18/2022	(771018 - Confidential)	Exhibit Objections, Appendix 2 to Complainants' High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/18/2022	(771019 - Confidential)	Exhibit Objections, Appendix 3 to Complainants' High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/18/2022	(771020 - Confidential)	Exhibit Objections, Appendix 4 to Complainants' High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/18/2022	(771021 - Confidential)	Exhibit Objections, Appendix 5 to Complainants' High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/18/2022	(771022 - Confidential)	Exhibit Objections, Appendix 6 to Complainants' High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/18/2022	(771023 - Public)	Motion, 1276-043 33 Complainants' Unopposed Motion for Partial Termination by Withdrawal of Certain Claims, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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05/20/2022	(771209 - Public)	Motion, 1276-044 36 Complainants' Motion in Limine No. 5 to Preclude Expert Testimony and Evidence regarding Claim Constructions of "Openings," "Over," "User" and "Array", filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/20/2022	(771234 - Public)	ID/RD - Other Than Final on Violation, 1276-043 33 Initial Determination Granting Complainants' Second Unopposed Motion for Partial Termination by Withdrawal of Certain Claims, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
05/23/2022	(771333 - Public)	Order, 34 Evidentiary Hearing Procedures; Amending Ground Rules, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
05/23/2022	(771337 - Public)	Order, 1276-012 31 Denying Respondent's Motion for Sanctions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
05/23/2022	(771338 - Public)	Order, 1276-027 32 Granting-in-Part and Denying-in-Part Respondent's Motion to Strike and Preclude Reliance on Complainants' Domestic Industry Contentions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
05/24/2022	(771436 - Confidential)	Motion Response/Reply, 1276-038 Complainants' Opposition to Respondent Apple Inc.'s Motion in Limine No. 2 to Preclude Evidence or Argument Concerning Alleged Copying by Apple, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/24/2022	(771449 - Public)	Motion, 1276-038 41 Respondent Apple Inc.'s Motion in Limine No. 2 to Preclude Evidence or Argument Concerning Alleged Copying by Apple, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771451 - Public)	Motion, 1276-042 Respondent Apple Inc.'s Motion in Limine No. 1 to Exclude Evidence and Argument regarding Post-Complaint Developments and Activities, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771453 - Public)	Motion, 1276-039 Respondent Apple Inc.'s Motion in Limine No. 3 to Exclude Economic Prong-Related Evidence Not Provided during Discovery, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771455 - Public)	Motion, 1276-037 38 Respondent Apple Inc.'s Motion in Limine No. 4 to Preclude Robert Stoll from Presenting Improper Expert Opinion, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771457 - Confidential)	Exhibit Objections, Respondent Apple Inc.'s Responses to Complainants' High Priority Objections, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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05/24/2022	(771458 - Confidential)	Response/Submission to ALJ Order, Respondent Apple Inc.'s Response to Complainants' Request for Receipt of Evidence without a Sponsoring Witness, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771460 - Confidential)	Motion Response/Reply, 1276-037 Complainants' Opposition to Respondent Apple Inc.'s Motion in Limine No. 4, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/24/2022	(771461 - Confidential)	Motion Response/Reply, 1276-036 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 1 to Exclude Kansas State Physical Devices, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771462 - Confidential)	Motion Response/Reply, 1276-041 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 2, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771464 - Public)	Motion Response/Reply, 1276-035 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 3, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771465 - Confidential)	Motion Response/Reply, 1276-040 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 4, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771468 - Confidential)	Motion Response/Reply, 1276-044 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 5, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/24/2022	(771469 - Confidential)	Motion Response/Reply, 1276-042 Complainants' Opposition to Respondent Apple Inc.'s Motion in Limine No. 1 to Exclude Evidence and Arguments regarding Post-Complaint Developments and Activities, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/24/2022	(771471 - Confidential)	Motion Response/Reply, 1276-039 Complainants' Opposition to Respondent Apple Inc.'s Motion in Limine No. 3 to Preclude Evidence Not Provided during Discovery Relating to the Economic Prong of the Domestic Industry Requirement, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/24/2022	(771483 - Confidential)	Exhibit Objections, Complainants' Response to Respondent Apple Inc.'s High Priority Objections, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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05/25/2022	(771492 - Public)	Exhibit Objections, Respondent Apple Inc.'s High Priority Objections, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/25/2022	(771620 - Confidential)	Motion, 1276-045 45 Motion to Quash Trial Subpoena Ad Testificandum Directed to Ueyn Block, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/26/2022	(771623 - Public)	Motion, 1276-036 39 Complainants' Motion in Limine No. 1 to Exclude the Kansas State Physical Devices, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/26/2022	(771624 - Public)	Motion, 1276-041 40 Complainants' Motion in Limine No. 2 to Preclude Apple from Introducing Evidence regarding Insufficiently Identified Defenses, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/26/2022	(771625 - Public)	Motion, 1276-035 42 Complainants' Motion in Limine No. 3 to Preclude Apple's Third-Party Witness Robert Rowe from Testifying at the Hearing, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/26/2022	(771626 - Public)	Motion, 1276-040 44 Complainants' Motion in Limine No. 4 to Exclude Apple Watch Series 0 as Prior Art to the '745 Patent, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/26/2022	(771627 - Public)	Exhibit Objections, Complainants' High Priority Objections, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/26/2022	(771629 - Public)	Motion, 1276-016 Complainants' Motion for Leave to File a Notice of Supplemental Facts regarding Motion to Compel, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/26/2022	(771630 - Public)	Motion Response/Reply, 1276-024 Complainants' Opposition to Respondent's Motion for Protective Order to Preclude Depositions of Tim Cook and Jeff Williams, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/27/2022	(771752 - Public)	Brief Filed With ALJ, Complainants' Pre-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/27/2022	(771753 - Public)	Motion Response/Reply, 1276-020 Complainants' Opposition to Respondent Apple Inc.'s Motion for Leave to File a Notice of Supplemental Facts regarding Its Motion for Sanctions, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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05/27/2022	(771819 - Public)	Pre-Hearing Statement, Respondent Apple Inc.'s Corrected Pre-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/27/2022	(771840 - Public)	Motion, 1276-046 Complainants' Request for Closed Session of Evidentiary Hearing, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/27/2022	(771845 - Public)	Motion, 1276-047 Complainants' Request for Closed Session of Evidentiary Hearing, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771854 - Confidential)	Motion, 1276-036 Supplement to Complainants' Motion in Limine No. 1, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771855 - Confidential)	Motion, 1276-041 Supplement to Complainants' Motion in Limine No. 2, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771856 - Confidential)	Motion, 1276-040 Supplement to Complainants' Motion in Limine No. 4, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771857 - Confidential)	Motion, 1276-044 Supplement to Complainants' Motion in Limine No. 5, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771858 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of David Gringer, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/31/2022	(771861 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Ari Feinstein, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771868 - Public)	Motion Response/Reply, 1276-042 Complainants' Opposition to Respondent Apple Inc.'s Motion in Limine No. 1 to Exclude Evidence and Arguments regarding Post-Complaint Developments and Activities, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771869 - Public)	Motion Response/Reply, 1276-038 Complainants' Opposition to Respondent Apple Inc.'s Motion in Limine No. 2 to Preclude Evidence or Argument Concerning Alleged Copying by Apple, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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05/31/2022	(771870 - Public)	Motion Response/Reply, 1276-039 Complainants' Opposition to Motion in Limine No. 3 to Preclude Evidence Not Provided during Discovery Related to the Economic Prong of the Domestic Industry Requirement, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771871 - Public)	Motion Response/Reply, 1276-037 Complainants' Opposition to Respondent Apple Inc.'s Motion in Limine No. 4 to Preclude Robert Stoll from Presenting Improper Expert Opinion, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
05/31/2022	(771872 - Public)	Exhibit Objections, Complainants' Response to Respondent Apple Inc.'s High Priority Objections, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/01/2022	(771986 - Confidential)	Motion Response/Reply, 1276-045 Complainants' Opposition to Respondent Apple Inc.'s Motion to Quash Trial Subpoena Ad Testificandum Directed to Ueyn Block (Motion No., filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/01/2022	(772011 - Confidential)	Order, 1276-034 35 Granting-in-Part and Denying-in-Part Respondent's Motion to Strike and Preclude Reliance upon Complainants' Untimely Disclosed Fact Discovery and Expert Opinions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/01/2022	(772014 - Confidential)	Order, 1276-044 36 Granting-in-Part and Denying-in-Part Complainants' Motion in Limine No. 5 to Preclude Expert Testimony and Evidence regarding Claim Constructions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/01/2022	(772015 - Public)	Order, 1276-042 37 Denying Respondent's Motion in Limine No. 1 to Exclude Evidence and Argument regarding Post-Complaint Developments and Activities, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/01/2022	(772053 - Confidential)	Order, 1276-037 38 Granting-in-Part and Denying-in-Part Respondent's Motion in Limine No. 4 to Preclude Robert Stoll from Presenting Certain Expert Opinion, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/01/2022	(772056 - Confidential)	Order, 1276-036 39 Denying Complainants' Motion in Limine No. 1 to Exclude Kansas State Physical Devices, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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06/01/2022	(772058 - Confidential)	Order, 1276-041 40 Denying Complainants' Motion in Limine No. 2 to Preclude Evidence regarding Insufficiently Identified Defenses, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/02/2022	(772113 - Public)	Motion Response/Reply, 1276-036 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 1 to Exclude Kansas State Physical Devices, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/02/2022	(772115 - Public)	Motion Response/Reply, 1276-041 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 2, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/02/2022	(772116 - Public)	Motion Response/Reply, 1276-041 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 4, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/02/2022	(772117 - Public)	Motion Response/Reply, 1276-044 Respondent Apple Inc.'s Opposition to Complainants' Motion in Limine No. 5, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/02/2022	(772119 - Public)	Exhibit Objections, Respondent Apple Inc.'s Responses to Complainants' High Priority Objections, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/02/2022	(772121 - Public)	Response/Submission to ALJ Order, Respondent Apple Inc.'s Response to Complainants' Request for Receipt of Evidence without a Sponsoring Witness, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/02/2022	(772175 - Confidential)	Order, 1276-038 41 Denying Respondent's Motion in Limine No. 2 to Preclude Evidence or Argument Concerning Alleged Copying by Apple, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/02/2022	(772177 - Confidential)	Order, 1276-035 42 Denying Complainants' Motion in Limine No. 3 to Preclude Robert Rowe from Testifying at the Hearing, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/02/2022	(772179 - Confidential)	Order, 1276-039 43 Denying Respondent's Motion in Limine No. 3 to Exclude Economic Prong-Related Evidence Not Provided during Discovery, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/03/2022	(772219 - Confidential)	Order, 1276-040 44 Denying Complainants' Motion in Limine No. 4 to Exclude Apple Watch Series 0 as Prior Art to the '745 Patent, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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06/03/2022	(772220 - Confidential)	Order, 1276-045 45 Denying Respondent's Motion to Quash Trial Subpoena Ad Testificandum Directed to Ueyn Block, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/03/2022	(772234 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Jadya Pak, Anthony DiLonardo, and Michael Kelley, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/03/2022	(772242 - Public)	Notice of Appearance, Notice of Limited Appearance of Fish & Associates PC on Behalf of Non-Party Robert Rowe; Designation of Timothy J. Rawson as Lead Counsel, filed by Tim Rawson of Fish & Associates PC, on behalf of Robert Rowe
06/03/2022	(772272 - Confidential)	Order, 46 Granting-in-Part and Denying-in-Part Complainants' Request for Receipt of Evidence without a Sponsoring Witness, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/03/2022	(772287 - Confidential)	Order, 47 Addressing Complainants' High Priority Objections, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/03/2022	(772303 - Confidential)	Order, 48 Addressing Respondents' High Priority Objections, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/06/2022	(772313 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Jamie Laird, Rebecca Lavernoch, and Phil Cho, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/06/2022	(772314 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of James Lyons and Jennifer John, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/06/2022	(772315 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Emily Scherker, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/06/2022	(772316 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Syd Sisante and Victor Lee, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/06/2022	(772368 - Confidential)	Response/Submission to ALJ Order, Complainants' Request for Receipt of Evidence without a Sponsoring Witness, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/06/2022	(772372 - Public)	Response/Submission to ALJ Order, Complainants' Request for Receipt of Evidence without a Sponsoring Witness, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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06/06/2022	(772379 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Mary Kate Blazofsky, Tawanna Bussey, and Scott Butler, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/09/2022	(772665 - Public)	Other, Joint Stipulation regarding Labeling of Claim Limitations, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
06/09/2022	(772681 - Confidential)	Transcript, Pre-Hearing Conference (Pages 1-91) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/09/2022	(772683 - Public)	Transcript, Pre-Hearing Conference (Pages 1-91) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/09/2022	(772771 - Confidential)	Transcript, Hearing (pages 597-861) with excerpts, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/09/2022	(772772 - Public)	Transcript, Hearing (pages 597-861) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/09/2022	(772773 - Confidential)	Transcript, Hearing (Pages 283-596) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/09/2022	(772774 - Public)	Transcript, Hearing (Pages 283-596) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/09/2022	(772782 - Confidential)	Transcript, Hearing (Pages 1-282) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/09/2022	(772783 - Public)	Transcript, Hearing (Pages 1-282) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/10/2022	(772826 - Public)	Notice, 33 Commission Determination Not to Review an Initial Determination Granting Complainants' Second Unopposed Motion for Partial Withdrawal of Certain Claims, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
06/10/2022	(772835 - Confidential)	Transcript, Hearing (Pages 862-1167) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/10/2022	(772836 - Public)	Transcript, Hearing (Pages 862-1167) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/13/2022	(772982 - Public)	Transcript, Hearing (pp 1168 through 1450) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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06/13/2022	(772984 - Confidential)	Transcript, Hearing (pp 1168 through 1450) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/13/2022	(773008 - Public)	Order, 49 Regarding Post-Hearing Briefs, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/13/2022	(773024 - Public)	Voting Sheet, GC-22-176, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
06/14/2022	(773129 - Public)	Order, 1276-034 35 Granting-in-Part and Denying-in-Part Respondent's Motion to Strike and Preclude Reliance upon Complainants' Untimely Disclosed Fact Discovery and Expert Opinions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/14/2022	(773131 - Public)	Order, 1276-044 36 Granting-in-Part and Denying-in-Part Complainants' Motion in Limine No. 5 to Preclude Expert Testimony and Evidence regarding Claim Constructions, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/14/2022	(773133 - Public)	Order, 1276-037 38 Granting-in-Part and Denying-in-Part Respondent's Motion in Limine No. 4 to Preclude Robert Stoll from Presenting Certain Expert Opinion, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/14/2022	(773134 - Public)	Order, 1276-036 39 Denying Complainants' Motion in Limine No. 1 to Exclude Kansas State Physical Devices, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/14/2022	(773135 - Public)	Order, 1276-041 40 Denying Complainants' Motion in Limine No. 2 to Preclude Evidence regarding Insufficiently Identified Defenses, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/15/2022	(773186 - Confidential)	Motion, 1276-048 Joint Motion to Reopen the Evidentiary Record and Identification of Hearing Demonstratives, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
06/16/2022	(773256 - Public)	Order, 1276-038 41 Denying Respondent's Motion in Limine No. 2 to Preclude Evidence or Argument Concerning Alleged Copying by Apple, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/16/2022	(773257 - Public)	Order, 1276-035 42 Denying Complainants' Motion in Limine No. 3 to Preclude Robert Rowe from Testifying at the Hearing, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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06/16/2022	(773259 - Public)	Order, 1276-039 43 Denying Respondent's Motion in Limine No. 3 to Exclude Economic Prong-Related Evidence Not Provided during Discovery, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/16/2022	(773261 - Public)	Order, 1276-040 44 Denying Complainants' Motion in Limine No. 4 to Exclude Apple Watch Series 0 as Prior Art to the '745 Patent, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/16/2022	(773264 - Public)	Order, 1276-045 45 Denying Respondent's Motion to Quash Trial Subpoena Ad Testificandum Directed to Ueyn Block, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/16/2022	(773265 - Public)	Order, 46 Granting-in-Part and Denying-in-Part Complainants' Request for Receipt of Evidence without a Sponsoring Witness, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/16/2022	(773266 - Public)	Order, 47 Addressing Complainants' High Priority Objections, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/16/2022	(773267 - Public)	Order, 48 Addressing Respondents' High Priority Objections, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/16/2022	(773324 - Confidential)	Order, 1276-048 50 Granting-in-Part and Denying-in-Part Joint Motion to Reopen the Evidentiary Record for the Admission of Exhibits, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/17/2022	(773415 - Public)	Motion, 1276-045 Motion to Quash Trial Subpoena Ad Testificandum Directed to Ueyn Block, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/17/2022	(773416 - Public)	Motion Response/Reply, 1276-045 Complainants' Opposition to Respondent Apple Inc.'s Motion to Quash Trial Subpoena Ad Testificandum Directed to Ueyn Block, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/21/2022	(773563 - Confidential)	Motion, 1276-049 Joint Motion to Reopen the Evidentiary Record, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
06/23/2022	(773735 - Confidential)	Order, 1276-049 51 Granting Joint Motion to Reopen the Evidentiary Record to Substitute Certain Testimony, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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06/24/2022	(773878 - Public)	Motion, 1276-050 52 Complainants' Unopposed Motion to Correct Hearing Transcript, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/27/2022	(773963 - Public)	Exhibit List, Complainants' Final Exhibit Lists, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/27/2022	(774000 - Confidential)	Brief Filed With ALJ, Complainants' Initial Post-Hearing Brief, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/27/2022	(774010 - Public)	Order, 1276-050 52 Granting Complainants' Unopposed Motion to Correct Hearing Transcript, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/27/2022	(774025 - Confidential)	Brief Filed With ALJ, Respondent Apple Inc.'s Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/28/2022	(774034 - Confidential)	Transcript, Revised and Corrected Hearing (pages 1168-1459), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/28/2022	(774035 - Public)	Transcript, Revised and Corrected Hearing (pages 1168-1459), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
06/30/2022	(774290 - Public)	Motion, 1276-051 1276 Respondent Apple Inc.'s Motion to Reopen Evidentiary Record, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/01/2022	(774416 - Confidential)	Motion, 1276-052 57 Complainants' Motion to Strike Unadmitted Evidence and Related Arguments in Apple's Initial Post-Hearing Brief and Request for Shortened Briefing Schedule, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/01/2022	(774465 - Confidential)	Motion, 1276-053 54 Respondent Apple Inc.'s Motion for Leave to File a Corrected Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/05/2022	(774515 - Public)	Motion Response/Reply, 1276-052 Respondent Apple Inc.'s Opposition to Complainants' Request for Shortened Response Time, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/05/2022	(774554 - Confidential)	Motion Response/Reply, 1276-051 Complainants' Opposition to Respondent Apple Inc.'s Motion to Reopen the Evidentiary Record, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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07/05/2022	(774586 - Public)	Exhibit List, Respondent's Final Exhibit Lists, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/06/2022	(774617 - Public)	Order, 1276-052 53 Granting-in-Part Request for Shortened Response Time for Complainants' Motion to Strike, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
07/07/2022	(774817 - Public)	Motion Response/Reply, 1276-053 Complainants' Response to Respondent Apple Inc.'s Motion for Leave to File a Corrected Post-Hearing Brief, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/07/2022	(774820 - Confidential)	Motion, 1276-054 55 Complainants' Unopposed Motion for Leave to File Corrected Post-Hearing Brief, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/08/2022	(774962 - Confidential)	Motion Response/Reply, 1276-051 Respondent Apple Inc.'s Reply in Support of Its Motion to Reopen the Evidentiary Record, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/11/2022	(775058 - Confidential)	Brief Filed With ALJ, Complainants' Reply Post-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/11/2022	(775073 - Confidential)	Brief Filed With ALJ, Respondent Apple Inc.'s Reply Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/11/2022	(775075 - Public)	Exhibit List, Respondent's Corrected Final Exhibit Lists, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/12/2022	(775090 - Confidential)	Transcript, Revised and Corrected Hearing (pages 1-282), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
07/12/2022	(775091 - Public)	Transcript, Revised and Corrected Hearing (pages 1-282), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
07/12/2022	(775095 - Confidential)	Transcript, Revised and Corrected Hearing (pages 597-861), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
07/12/2022	(775096 - Public)	Transcript, Revised and Corrected Hearing (pages 597-861), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
07/12/2022	(775168 - Public)	Brief Filed With ALJ, Complainants' Initial Post-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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07/12/2022	(775200 - Confidential)	Motion Response/Reply, 1276-052 Respondent Apple Inc.'s Opposition to Complainants' Motion to Strike Unadmitted Evidence and Related Arguments in Apple's Initial Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/13/2022	(775226 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Allison Que and Brian Jacobsmeyer., filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/13/2022	(775269 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/14/2022	(775366 - Public)	Order, 1276-053 54 Granting Respondent's Motion for Leave to File a Corrected Post-Hearing Brief, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
07/14/2022	(775367 - Public)	Order, 1276-054 55 Granting Complainants' Unopposed Motion for Leave to File Corrected Post-Hearing Brief, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
07/14/2022	(775422 - Confidential)	Brief Filed With ALJ, Complainants' Corrected Initial Post-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/15/2022	(775528 - Confidential)	Motion Response/Reply, 1276-052 Complainants' Reply in Support of Motion to Strike Unadmitted Evidence and Related Arguments in Apple's Initial Post-Hearing Brief and Request for Shortened Briefing Schedule, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
07/15/2022	(775529 - Public)	Motion, 1276-049 Joint Motion to Reopen Evidentiary Record, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
07/15/2022	(775530 - Public)	Motion, 1276-049 Joint Motion to Reopen the Evidentiary Record and Identification of Hearing Demonstratives, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Masimo Corporation, Cercacor Laboratories, Inc., and Apple Inc.
07/15/2022	(775537 - Public)	Motion, 1276-053 Respondent Apple Inc.'s Motion to File a Corrected Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/25/2022	(776163 - Public)	Brief Filed With ALJ, Complainants' Reply Post-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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07/25/2022	(776166 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Reply Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/28/2022	(776462 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Corrected Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/18/2022	(778304 - Public)	Motion, 1276-055 Complainants' Motion to Modify the Protective Order, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/19/2022	(778354 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of James Bor-Zale, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/22/2022	(778395 - Public)	Motion, 1276-054 Complainants' Unopposed Motion for Leave to File Corrected Post-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/22/2022	(778396 - Public)	Brief Filed With ALJ, Complainants' Corrected Initial Post-Hearing Brief, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/29/2022	(778983 - Public)	Motion Response/Reply, 1276-055 Respondent Apple Inc's Opposition to Complainants' Motion to Modify Protective Order, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
08/31/2022	(779167 - Confidential)	Order, 1276-051 56 Granting Respondent's Motion to Reopen the Evidentiary Record to Admit RX-1397C and RX-1447C, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
08/31/2022	(779168 - Confidential)	Order, 1276-052 57 Granting-in-Part and Denying-in-Part Complainants' Motion to Strike Unadmitted Evidence and Related Arguments in Respondent's Post-Hearing Brief; Denying Request for Judicial Notice, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
08/31/2022	(779170 - Public)	Order, 1276-049 51 Granting Joint Motion to Reopen the Evidentiary Record to Substitute Certain Testimony, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/01/2022	(779274 - Public)	Motion, 1276-055 Complainants' Reply in Support of Motion to Modify Protective Order, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/02/2022	(779376 - Confidential)	Brief Filed With ALJ, Respondent Apple Inc.'s Second Corrected Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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09/02/2022	(779379 - Confidential)	Brief Filed With ALJ, Respondent Apple Inc.'s Corrected Post-Hearing Reply Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/07/2022	(779613 - Confidential)	Transcript, Evidentiary Hearing (Pages 1168-1459) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/07/2022	(779614 - Public)	Transcript, Evidentiary Hearing (Pages 1168-1459) (with excerpts), filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/12/2022	(779937 - Public)	Order, 1276-051 56 Granting Respondent's Motion to Reopen the Evidentiary Record to Admit RX-1397C and RX-1447C, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/12/2022	(779938 - Public)	Order, 1276-052 57 Granting-in-Part and Denying-in-Part Complainants' Motion to Strike Unadmitted Evidence and Related Arguments in Respondent's Post-Hearing Brief; Denying Request for Judicial Notice, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/12/2022	(779940 - Public)	ID/RD - Other Than Final on Violation, 58 Initial Determination Extending Target Date by Six Weeks, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
09/14/2022	(780238 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Corrected Reply Post-Hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/15/2022	(780239 - Public)	Brief Filed With ALJ, Respondent Apple Inc.'s Second Corrected Post-hearing Brief, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/28/2022	(781182 - Public)	Exhibit, Post-Trial, CX-0004 - CX-1760, filed by Joseph R. Re of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/28/2022	(781183 - Confidential)	Exhibit, Post-Trial, CX-0006C - CX-1805C, filed by Joseph R. Re of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/28/2022	(781184 - Confidential)	Exhibit, Post-Trial, CDX-0001C - CDX-0019C, filed by Joseph R. Re of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/28/2022	(781185 - Public)	Exhibit, Post-Trial, CPX-0014a - CPX-0191, filed by Joseph R. Re of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/28/2022	(781186 - Confidential)	Exhibit, Post-Trial, CPX-0012aC - CPX-0181C, filed by Joseph R. Re of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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09/28/2022	(781187 - Public)	Exhibit, Post-Trial, JX-0001 - JX-0010, filed by Joseph R. Re of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
09/28/2022	(781199 - Public)	Exhibit, Post-Trial, RX-0023 - RX-1467, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/28/2022	(781203 - Confidential)	Exhibit, Post-Trial, RX-0041C - RX-1470C, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/28/2022	(781204 - Public)	Exhibit, Post-Trial, RDX-3 - RDX-12, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/28/2022	(781205 - Confidential)	Exhibit, Post-Trial, RDX-1C - RDX-13C, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
09/28/2022	(781206 - Public)	Exhibit, Post-Trial, RPX-0001 - RPX-0041, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
10/03/2022	(781510 - Public)	Notice, 58 Commission Determination Not to Review an Initial Determination Extending the Target Date, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
10/12/2022	(782099 - Public)	Voting Sheet, GC-22-316, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
10/24/2022	(782882 - Public)	ID/RD - Other Than Final on Violation, 59 Initial Determination Extending Target Date, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
11/10/2022	(784275 - Public)	Notice, Commission Determination Not to Review an Initial Determination Extending the Target Date, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
11/17/2022	(784759 - Public)	Order, 1276-055 60 Denying Complainants' Motion to Modify Protective Order, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
12/09/2022	(785999 - Public)	ID/RD - Other Than Final on Violation, 61 Initial Determination Extending Target Date, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
12/12/2022	(786127 - Public)	Voting Sheet, GC-22-358, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
01/06/2023	(787448 - Public)	Notice, 61 Commission Determination Not to Review an Initial Determination Extending the Target Date, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
01/10/2023	(787648 - Public)	Notice, Notice of Final Initial Determination on Violation of Section 337, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge

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01/10/2023	(787653 - Confidential)	ID/RD - Final on Violation, Final Initial Determination on Violation of Section 337, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/12/2023	(787858 - Public)	Voting Sheet, GC-22-396, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
01/13/2023	(787970 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Sean Wesp and Deanna Tanner Okum, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/17/2023	(788049 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Amanda Taylor, filed by Jonathan Bachand of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/19/2023	(788269 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Melanie Bostwick, Mark Davies, and Jordan Coyle, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/23/2023	(788456 - Confidential)	Petition for Review; and Response to, Complainants' Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/23/2023	(788457 - Confidential)	Petition for Review; and Response to, Complainants' Summary of Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/23/2023	(788470 - Confidential)	Petition for Review; and Response to, Respondent Apple Inc.'s Petition for Review of the Initial Determination of Violation of Section 337, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/24/2023	(788474 - Confidential)	Petition for Review; and Response to, Respondent Apple Inc.'s Summary of Petition for Review of the Initial Determination of Violation of Section 337, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/24/2023	(788506 - Confidential)	ID/RD - Final on Violation, Recommended Determination on Remedy and Bonding, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
01/25/2023	(788544 - Public)	Notice, Request for Submissions on the Public Interest, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
01/30/2023	(788891 - Public)	Notice of Appearance, Notice of Change of Address for Counsel Law Firm Wilmer Cutler Pickering Hale and Dorr LLP on Behalf of Apple Inc., filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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01/31/2023	(788976 - Public)	Notice, 88 FR 6312 F.R. Notice of Request for Submissions on the Public Interest, filed by Katherine M. Hiner of USITC, on behalf of Office of the Secretary
01/31/2023	(789029 - Public)	Brief on Review/Remedy, Comments from Dr. Adam Waddell, filed by Adam Waddell of Hartford Hospital, on behalf of Hartford Hospital
01/31/2023	(789044 - Confidential)	Petition for Review; and Response to, Complainants' Response to Apple Inc.'s Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/31/2023	(789045 - Confidential)	Petition for Review; and Response to, Complainants' Summary of Response to Apple Inc.'s Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/31/2023	(789061 - Confidential)	Petition for Review; and Response to, Respondent Apple Inc.'s Response to Complainants' Petition for Review, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/31/2023	(789067 - Confidential)	Petition for Review; and Response to, Respondent Apple Inc.'s Summary of Its Response to Complainants' Petition for Review, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/01/2023	(789080 - Public)	Brief on Review/Remedy, Public Interest Statement Points supporting Masimo, filed by Christopher McCarthy of Christopher McCarthy, on behalf of Christopher McCarthy
02/02/2023	(789331 - Public)	Petition for Review; and Response to, Respondent Apple Inc.'s Petition for Review of the Initial Determination of Violation of Section 337, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/02/2023	(789332 - Public)	Petition for Review; and Response to, Respondent Apple Inc.'s Summary of Petition for Review of the Initial Determination of Violation of Section 337, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/03/2023	(789338 - Public)	Brief on Review/Remedy, Comments for Inv. 337-1276, filed by Cynthia Persaud of Cynthia Persaud, on behalf of Cynthia Persaud
02/03/2023	(789339 - Public)	Petition for Review; and Response to, Complainants' Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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02/03/2023	(789340 - Public)	Petition for Review; and Response to, Complainants' Summary of Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/07/2023	(789795 - Public)	ID/RD - Final on Violation, Final Initial Determination on Violation of Section 337, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
02/10/2023	(790070 - Public)	Notice of Withdrawal of Appearance, Notices of Withdrawal of Appearance of Jordan Coyle, Mark Davies, and Mel Bostwick from Orrick, Herrington and Sutcliffe LLP on Behalf of Apple Inc., filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/10/2023	(790079 - Public)	ID/RD - Final on Violation, Recommended Determination on Remedy and Bonding, filed by Monica Bhattacharyya of USITC, on behalf of Administrative Law Judge
02/10/2023	(790113 - Public)	Petition for Review; and Response to, Complainants' Response to Apple Inc.'s Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/10/2023	(790115 - Public)	Petition for Review; and Response to, Complainants' Summary of Response to Apple Inc.'s Petition for Review of the Final Initial Determination on Violation of Section 337, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/13/2023	(790123 - Public)	Petition for Review; and Response to, Respondent Apple Inc.'s Response to Complainants' Petition for Review, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/13/2023	(790124 - Public)	Petition for Review; and Response to, Respondent Apple Inc.'s Summary of Its Response to Complainants' Petition for Review, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/15/2023	(790394 - Public)	Brief on Review/Remedy, Letter of Support from Cure HHT, filed by Marianne Clancy of Cure HHT, on behalf of Cure HHT
02/16/2023	(790510 - Public)	Brief on Review/Remedy, Letter in Support of Apple and Public Interest, filed by Robert M. Watcher of Department of Medicine, UCSF, on behalf of Robert M. Wachter
02/17/2023	(790602 - Public)	Brief on Review/Remedy, Support for the Apple Watch for Use in Tracking Physiologic Features in Medical Patients, filed by Russell Bowler of National Jewish Health, on behalf of National Jewish Health
02/21/2023	(790641 - Public)	Brief on Review/Remedy, Letter of Support for Apple Watch, filed by Jessica Golbus of University of Michigan Health, on behalf of University of Michigan Health

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02/21/2023	(790642 - Public)	Brief on Review/Remedy, Letter of Support, filed by Mellanie Hills of StopAFIB.org, on behalf of StopAFIB.org
02/21/2023	(790787 - Public)	Brief on Review/Remedy, Public Interest Statement of Josh Malone, filed by Josh Malone of Josh Malone, on behalf of Josh Malone
02/22/2023	(790883 - Public)	Brief on Review/Remedy, Public Interest Comments of David Albert, filed by David Albert of AliveCor, Inc., on behalf of AliveCor, Inc.
02/22/2023	(790884 - Public)	Brief on Review/Remedy, Public Interest Statement of Kevin R. Ward, filed by Kevin R. Ward of University of Michigan Medicine, on behalf of University of Michigan Medicine
02/23/2023	(790962 - Public)	Brief on Review/Remedy, Public Interest Comments of Bill Carpou from Octane, filed by Bill Carpou of Octane, on behalf of Octane
02/23/2023	(790991 - Public)	Brief on Review/Remedy, Public Interest Statement of Ryan Drant from Questa Capital, filed by Ryan Drant of Questa Capital, on behalf of Questa Capital
02/23/2023	(791012 - Public)	Brief on Review/Remedy, Public Comments from California Life Sciences, filed by Mike Guerra of California Life Sciences, on behalf of California Life Sciences
02/23/2023	(791041 - Public)	Brief on Review/Remedy, Public Interest Comments of US Inventor, Inc., filed by Randall Landreneau of US Inventor, on behalf of US Inventor
02/23/2023	(791047 - Public)	Brief on Review/Remedy, Public Interest Letter from Congressman Buck, filed by Ken Buck of Congress of the United States, on behalf of Congress of the United States
02/23/2023	(791048 - Public)	Brief on Review/Remedy, Public Interest Comments from Innovation Alliance, filed by Brian Pomper of Innovation Alliance, on behalf of Innovation Alliance
02/23/2023	(791050 - Public)	Brief on Review/Remedy, Complainants' Statement on the Public Interest, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
02/23/2023	(791054 - Public)	Brief on Review/Remedy, Statement of Third Party Computer and Communications Industry Association in Response to the Commission's January 31, 2023, Notice of Request for Statements on the Public Interest, filed by Joshua Landau of Computer and Communications Industry Association, on behalf of Computer and Communications Industry Association
02/23/2023	(791060 - Public)	Brief on Review/Remedy, Letter in Support of Apple Watch, filed by Stephen Ruoss of Stanford University Medical Center, on behalf of Stanford University Medical Center
02/23/2023	(791062 - Public)	Brief on Review/Remedy, Respondent Apple Inc.'s Public Interest Statement, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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02/23/2023	(791069 - Public)	Brief on Review/Remedy, Statement of Third Party Law Professors Adam Mossoff and Kristen Osenga in Response to the Commission's Notice of Request for Statements on the Public Interest and Reply to Respondent's Statement of February 22, 2023 Dated February 23, 2023, filed by Kristen Osenga of Adam Mossoff and Kristen Osenga, on behalf of Adam Mossoff and Kristen Osenga
02/27/2023	(791162 - Public)	Brief on Review/Remedy, Public Interest Statement of Non-Party Peter Pronovost, MD, filed by Peter Pronovost of University Hospitals, on behalf of University Hospitals
02/27/2023	(791163 - Public)	Brief on Review/Remedy, Public Interest Statement of Consumer Federation of America, filed by Mark Cooper of Consumer Federation of America, on behalf of Consumer Federation of America
02/27/2023	(791167 - Public)	Brief on Review/Remedy, Public Interest Statement of Non-Party of Medical Device Manufacturers Association (MDMA), filed by Mark Leahey of Medical Device Manufacturers Association (MDMA), on behalf of Medical Device Manufacturers Association (MDMA)
02/27/2023	(791175 - Public)	Brief on Review/Remedy, Public Interest Statement of Non-Party Patient Safety Movement Foundation, filed by Michael Ramsay of Patient Safety Movement Foundation, on behalf of Patient Safety Movement Foundation
02/27/2023	(791177 - Public)	Brief on Review/Remedy, Public Interest Statement of Non-Party Bobby Yazdani, filed by Bobby Yazdani of Cota Capital, on behalf of Cota Capital
02/27/2023	(791179 - Public)	Brief on Review/Remedy, Public Interest Statement of Non-Party Mitchell Goldstein, MD, filed by Mitchell Goldstein of Loma Linda University School of Medicine, on behalf of Loma Linda University School of Medicine
03/01/2023	(791476 - Public)	Brief on Review/Remedy, Statement of Non-Party American Heart Association on the Public Interest of the Recommended Remedial Orders but Not in Support of Any Party, filed by Robin Barnes of Scheef & Stone, LLP, on behalf of American Heart Association, Inc.
03/02/2023	(791567 - Public)	Brief on Review/Remedy, Public Interest Comments from C4IP, filed by Frank Cullen of Council for Innovation Promotion, on behalf of Council for Innovation Promotion
03/02/2023	(791665 - Public)	Brief on Review/Remedy, Public Interest Statement of Richard Milani, filed by Richard Milani of Ochsner Health System, on behalf of Ochsner Health System
03/03/2023	(791674 - Public)	Brief on Review/Remedy, Public Interest Statement of the Alliance for U.S. Startups and Inventors for Jobs, filed by Robert P. Taylor of The Alliance for U.S. Startups and Inventors for Jobs, on behalf of The Alliance of U.S. Startups and Inventors for Jobs

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03/03/2023	(791686 - Public)	Brief on Review/Remedy, Public Interest Statement of David Dinielli and Michael Enseki-Frank, filed by David Carter Dinielli of David Carter Dinielli and Michael Enseki-Frank, on behalf of David Carter Dinielli and Michael Enseki-Frank
03/07/2023	(791957 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Richard O'Neill, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/13/2023	(792344 - Public)	Notice, Commission Determination to Extend the Due Date for Determining Whether to Review the Final Initial Determination and to Extend the Target Date, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
03/14/2023	(792444 - Public)	Correspondence, Letter Requesting the Return of Physical Devices, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
03/22/2023	(792875 - Public)	Correspondence - USITC, Letter Granting Request to Return Physical Exhibits to Wilmer Cutler Pickering Hale and Dorr LLP, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
03/27/2023	(793192 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Benjamin Ho and Zachary Nemptow, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
04/06/2023	(793883 - Public)	Notice of Withdrawal of Appearance, Notice of Withdrawal of Appearance of Benjamin Ho from Wilmer Cutler Pickering Hale and Dorr LLP on Behalf of Apple Inc., filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/16/2023	(796515 - Public)	Notice, Commission Determination to Review in Part a Final Initial Determination; Request for Written Submissions on the Issues under Review and on Remedy, the Public Interest, and Bonding, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
05/16/2023	(796580 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Yifan Wang, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
05/19/2023	(796805 - Public)	Notice, 88 FR 32243 F.R. Notice of Commission Determination to Review in Part a Final Initial Determination; Request for Written Submissions on the Issues under Review and on Remedy, the Public Interest, and Bonding, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
06/05/2023	(797811 - Public)	Brief on Review/Remedy, Comments on Public Interest from Leslie A. Saxon, M.D., filed by Leslie A. Saxon of Keck School of Medicine, Univ. of Southern California, on behalf of Leslie A. Saxon

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06/05/2023	(797813 - Public)	Brief on Review/Remedy, Public Interest Comments from Rod S. Passman, M.D., M.S.C.E., filed by Rod S. Passman of Northwestern University Feinberg School of Medicine, on behalf of Rod S. Passman
06/05/2023	(797817 - Public)	Brief on Review/Remedy, Public Interest Comments from Nelson Freimer, filed by Nelson Freimer of Nelson Freimer, on behalf of Nelson Freimer
06/05/2023	(797826 - Public)	Brief on Review/Remedy, Public Interest Comments from Calum A. MacRae, MD, PhD, filed by Calum MacRae of Brigham & Women's Hospital and Harvard Medical School, on behalf of Brigham & Women's Hospital and Harvard Medical School
06/05/2023	(797827 - Public)	Brief on Review/Remedy, Public Interest Comments from Hugh Calkins, M.D., filed by Hugh Calkins of Johns Hopkins Hospital, on behalf of Johns Hopkins Hospital
06/05/2023	(797840 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Christian Dippon, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/05/2023	(797843 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Dirk van Leeuwen, Erdem Yenerdag, Claire Huther, Patricia A. Cunkelman, Blaine C. Helleloid, Jason Sabatelle, Casey Chong, and Tamara Lake, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/05/2023	(797853 - Confidential)	Brief on Review/Remedy, Complainants' Submission in Response to the Commission's May 15, 2023 Notice of Commission Determination to Review in Part, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/05/2023	(797854 - Public)	Brief on Review/Remedy, Public Interest Comments from Council for Innovation Promotion (C4IP), filed by Frank Cullen of Council for Innovation Promotion, on behalf of Council for Innovation Promotion
06/05/2023	(797870 - Confidential)	Brief on Review/Remedy, Respondent Apple Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/12/2023	(798257 - Public)	Brief on Review/Remedy, Public Interest Comments from Professors Francisco J. Valero-Cuevas, PhD and Najmedin Meshkati, PhD, CPE, filed by Francisco Valero Cuevas of University of Southern California, School of Engineering, on behalf of Francisco Valero Cuevas

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06/12/2023	(798353 - Confidential)	Brief on Review/Remedy, Complainants' Reply to Apple Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/12/2023	(798383 - Confidential)	Brief on Review/Remedy, Respondent Apple Inc.'s Reply to Complainants' Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/13/2023	(798476 - Public)	Voting Sheet, GC-23-075, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
06/15/2023	(798753 - Public)	Voting Sheet, GC-23-109, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
06/15/2023	(798756 - Public)	Brief on Review/Remedy, Respondent Apple Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/15/2023	(798775 - Public)	Brief on Review/Remedy, Complainants' Submission in Response to the Commission's May 15, 2023 Notice of Commission Determination to Review in Part, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/20/2023	(798906 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Mark A. Perry, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/22/2023	(799194 - Public)	Brief on Review/Remedy, Complainants' Reply to Apple Inc.'s Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
06/23/2023	(799211 - Public)	Brief on Review/Remedy, Respondent Apple Inc.'s Reply to Complainants' Response to the Commission's Notice to Review in Part a Final Initial Determination and Request for Written Submissions, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
06/26/2023	(799260 - Public)	Correspondence, Notice of Denial of Respondent Apple Inc.'s Requests for Rehearing of Decisions Denying Institution of Inter Partes Review for U.S. Patent No. 10,945,648, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.

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06/28/2023	(799503 - Public)	Notice of Withdrawal of Appearance, Notice of Withdrawal of Appearance of Richard Goldenberg from Wilmer Cutler Pickering Hale and Dorr LLP on Behalf of Apple Inc., filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
07/11/2023	(800089 - Public)	Voting Sheet, GC-23-172, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
07/11/2023	(800092 - Public)	Notice, Commission Determination to Extend the Target Date, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
08/17/2023	(802616 - Confidential)	Correspondence, Letter from Kendall M. Loebbaka to Secretary Barton Requesting the Return of Physical Exhibits, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
08/23/2023	(803004 - Public)	Correspondence - USITC, Letter Granting Request to Return Physical Exhibits to Knobbe, Martens, Olson & Bear LLP, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
09/25/2023	(804806 - Public)	Memorandum, CO89-VV-003 Recusal, filed by Amy A. Karpel of USITC, on behalf of Office of the Commissioner
10/02/2023	(805255 - Public)	Notice, Commission Determination to Extend the Target Date, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/03/2023	(805283 - Public)	Voting Sheet, GC-23-252, filed by Lisa R. Barton of USITC, on behalf of Office of General Counsel
10/10/2023	(805560 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Nathan Palacios, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
10/23/2023	(806724 - Public)	Notice, Commission Determination to Extend the Target Date, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/26/2023	(807001 - Public)	Notice, Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and a Cease and Desist Order; Termination of the Investigation, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/26/2023	(807002 - Public)	Order, Commission, Limited Exclusion Order for Apple, Inc., filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/27/2023	(807049 - Public)	Order, Commission, Cease and Desist Order for Apple, Inc., filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/27/2023	(807050 - Confidential)	Opinion, Commission, Commission Opinion, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary

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10/27/2023	(807051 - Public)	Correspondence - USITC, Letter to Chief Dax Terrill Informing Him of the Issuance of a Limited Exclusion Order by the Commission, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
10/30/2023	(807326 - Confidential)	Motion, 1276-056C Respondent Apple Inc.'s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/01/2023	(807517 - Confidential)	Correspondence - USITC, Letters from Chairman David S. Johanson to the President of the United States, Janet L. Yellen, Secretary of the Treasury, and Katherine Tai, United States Trade Representative Transmitting a Limited Exclusion Order and Cease and Desist Order, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
11/01/2023	(807518 - Public)	Correspondence - USITC, Letters from Chairman David S. Johanson to the President of the United States, Janet L. Yellen, Secretary of the Treasury, and Katherine Tai, United States Trade Representative Transmitting a Limited Exclusion Order and Cease and Desist Order, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
11/01/2023	(807536 - Public)	Notice, 88 FR 75032 F.R. Notice of Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and a Cease and Desist Order; Termination of the Investigation, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
11/02/2023	(807656 - Public)	Correspondence - USITC, Letter to Joseph R. Re regarding a Limited Exclusion Order, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
11/02/2023	(807663 - Confidential)	Correspondence, Letter to Secretary Barton regarding Confidential Treatment of CBP Letter, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/02/2023	(807664 - Public)	Correspondence, Letter to Secretary Barton regarding Confidential Treatment of CBP Letter, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/06/2023	(807796 - Public)	Correspondence, Letter from Sarah R. Frazier to Secretary Barton regarding Notice Letter, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/06/2023	(807840 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Michael A. Amon and Benjamin C. Elacqua, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.

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11/09/2023	(808262 - Confidential)	Motion Response/Reply, 1276-056C Complainants' Opposition to Respondent Apple Inc.'s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/13/2023	(808428 - Public)	Motion, 1276-056C Respondent Apple Inc.'s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/14/2023	(808521 - Public)	Opinion, Commission, Commission Opinion, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
11/20/2023	(808970 - Public)	Motion, 1276-057C Complainants' Request for Judicial Notice of Recent Regulatory Developments for Masimo W1 Watch, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/20/2023	(809031 - Public)	Motion, 1276-056C Respondent Apple Inc.'s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of Potential Government Shutdown, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
11/21/2023	(809050 - Public)	Motion Response/Reply, 1276-056C Complainants' Opposition to Apple Inc.'s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
11/29/2023	(809495 - Public)	Correspondence, Letter from Swaroop to Secretary Barton regarding October 27, 2023 Cease and Desist Order, filed by Sheila Swaroop of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
12/04/2023	(809720 - Confidential)	Correspondence - USITC, Letter to Chief Dax Terrill Informing Him of the Issuance of a Limited Exclusion Order by the Commission, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
12/04/2023	(809724 - Public)	Correspondence - USITC, Letter Approving WilmerHale Request for Confidential Treatment of CBP Letter, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
12/11/2023	(810157 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Kim Do, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
12/20/2023	(810736 - Public)	Notice, 1276-056C Commission Decision to Deny Respondent's Motion to Stay Remedial Orders Pending Appeal and/or in Light of Potential Government Shutdown, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary

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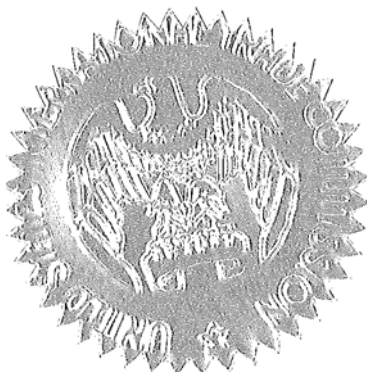
12/20/2023	(810738 - Public)	Order, Commission, 1276-056C Order Denying Respondent's Motion to Stay Remedial Orders Pending Appeal and/or in Light of Potential Government Shutdown, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
12/20/2023	(810741 - Confidential)	Opinion, Commission, Commission Opinion Denying Respondent's Motion to Stay the Remedial Orders, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
12/20/2023	(810788 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Justin Berns, filed by Kendall Loebbaka of Knobbe, Martens, Olson & Bear, on behalf of Masimo Corporation and Cercacor Laboratories, Inc.
01/03/2024	(811278 - Public)	Opinion, Commission, Commission Opinion, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary
01/04/2024	(811479 - Public)	PO Subscription, Agreement to Be Bound by the Protective Order of Scott M. Flanz, filed by Sarah Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/30/2024	(812916 - Confidential)	Compliance Report, Respondent Apple Inc.'s Report Pursuant to Section V of the Commission's October 26, 2023 Cease and Desist Order, filed by Sarah R. Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
01/31/2024	(813009 - Public)	Compliance Report, Respondent Apple Inc.'s Report Pursuant to Section V of the Commission's October 26, 2023 Cease and Desist Order, filed by Sarah R. Frazier of Wilmer Cutler Pickering Hale and Dorr LLP, on behalf of Apple Inc.
02/05/2024	(811081 - Public)	Other, Certified List 24-1285 Apple Inc. v. International Trade Commission, filed by Lisa R. Barton of USITC, on behalf of Office of the Secretary

Dated

02/05/2024



Lisa R. Barton
U.S. International Trade Commission



Certified to be a
true copy of the
Original
Secretary



UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that on this 5th of February, 2024 a true and correct copy of the attached **CERTIFIED LIST** was served via electronic service, upon the following:

On Behalf of Apple Inc.:

Mark D. Selwyn, Esq.
WILMER CUTLER PICKERING HALE AND DORR LLP
2600 El Camino Real, Suite 400
Palo Alto, CA 94306
Email: mark.selwyn@wilmerhale.com

On Behalf of Masimo Corporation and Cercacor Laboratories, Inc:

Joseph R. Re, Esq.
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Email: joseph.re@knobbe.com

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton, Secretary
U.S. International Trade Commission

Knobbe Martens

KNOBBE, MARTENS, OLSON & BEAR, LLP

1717 Pennsylvania Ave. N.W., Ste. 900, Washington D.C. 20006
T (202) 640-6400

Jonathan E. Bachand
Jonathan.Bachand@knobbe.com

June 29, 2021

Via EDIS

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

Re: *In the Matter of Certain Light-Based Physiological Measurement Devices and Components
Thereof*
ITC Inv. No. 337-TA-_____

Dear Secretary Barton:

Enclosed for filing, please find documents in support of a request by Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Complainants") that the U.S. International Trade Commission ("Commission") institute an investigation pursuant to the provisions of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 concerning certain light-based physiological measurement devices and components thereof. Please note that the Complaint, Complainants' Statement on the Public Interest, and certain Confidential Exhibits 11, 15-28, and 30 contain Confidential Business Information and, pursuant to the Commission's Rules of Practice and Procedure, a separate letter requesting confidential treatment of the information accompanies this filing.

On March 16, 2020, the Commission provided "notice that it is temporarily waiving and amending certain of the Commission's rules that required the filing of paper copies, CD-ROMS, and other physical media in section 337 investigations to address concerns about COVID-19." International Trade Commission, Temporary Changes to Filing Procedures, Federal Register Vol. 85, No. 54 (March 19, 2020). Specifically, the Commission approved the temporary amendment of various rules "to permit parties to file section 337 complaints, exhibits, attachments, and appendices, electronically." *Id.* Accordingly, Complainants' filing only contains electronic documents. Complainants' submission via EDIS includes the following documents:

1. One (1) electronic copy of Complainants' Verified Complaint, pursuant to Commission Rule 210.8(a)(1)(i);
2. A statement on the Public Interest Regarding the remedial orders sought by Complainants in the Verified Complaint, pursuant to Commission Rule 210(8)(b);
3. One (1) electronic copy of the public exhibits to the Verified Complaint pursuant to Commission Rules 210.8(a)(1) and 210.12(a)(9);
4. One (1) electronic copy of the confidential exhibits to the Verified Complaint, pursuant to Commission Rules 201(6)(c) and 210.8(a)(1)(ii);

5. One (1) electronic certified copy of each of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and 7,761,127 listed as Exhibits 1-5 in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9)(i);
6. One (1) electronic certified copy of each assignment for each of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and 7,761,127 listed as Exhibits 6-10 in the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9)(ii);
7. A certified copy of each of the prosecution histories for U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and 7,761,127, listed as Appendices A, C, D, E, and G in the Complaint, pursuant to 19 C.F.R. 210.12(c)(1);¹
8. A copy of each currently available cited technical reference identified in the prosecution histories of the Asserted Patents, identified as Appendices B, F, and H to the Complaint, pursuant to 19 C.F.R. 210.12(c)(2);² and
9. A letter of certification pursuant to 19 C.F.R. 201.6(b) and 210.5(d) requesting confidential treatment of information appearing in the Complaint, Complainants' Statement on the Public Interest, and Confidential Exhibits 11, 15-28, and 30.

Thank you for your attention to this filing. Please contact the undersigned if you have any questions.

Respectfully submitted,

/s/ Jonathan E. Bachand
Jonathan E. Bachand

¹ Due to USPTO errors, Complainants submitted certificates of correction to correct typographical errors in U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648 as originally issued. Although these certificates of correction have been approved, and certificates of correction have been issued for both U.S. Patent Nos. 10,912,501 and 10,945,648, the certificate of correction for U.S. Patent No. 10,912,502 has not yet issued. Additionally, Complainants have not yet received certified copies of the prosecution histories, which contain the information related to the certificates of correction for U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648. Accordingly, Complainants are submitting uncertified copies of the prosecution histories of U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648, and will submit certified copies once received. Once the certificate of correction issues for U.S. Patent No. 10,912,502, Complainants will seek leave to amend the complaint to add the certificate of correction.

² Because U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648 are related, there is a substantial overlap of the patents and applicable pages of each technical reference mentioned in the prosecution histories, and the copies are provided together in Appendix B.

APPX2347

ENTIRELY REDACTED

APPX2740-2758
ENTIRELY REDACTED

EXHIBIT 23

REDACTED

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
A user-worn device configured to non-invasively measure a physiological parameter of a user, the user worn device comprising:	<p>is a user-worn device configured to non-invasively measure a physiological parameter of a user. Confidential Declaration of Bilal Muhsin (“Muhsin Decl.”) ¶¶ 4, 6–7.</p>
a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;	<p>contains a first set of light emitting diodes that comprise an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
<p>a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;</p>	<p>[REDACTED] contains a second set of LEDs that are spaced apart from the first set of LEDs, and the second set of LEDs comprises at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
<p>four photodiodes arranged on an interior surface of the user-worn device and configured to receive light after attenuation by tissue of the user;</p>	<p>contains total photodiodes (circled in green below), which are arranged on an interior surface of the device and are configured to receive light after it is attenuated by the tissue of the user.</p>  <p>When worn by a user, the photodiodes face towards the skin in such a manner to reduce the receipt of light directly from the device's LEDs. In this manner, the photodiodes receive light after attenuation by tissue of the user and accordingly are configured to receive light after attenuation by tissue of the user. Muhsin Decl. ¶¶ 7–9, 11. This is shown in the below cross section of the device, which illustrates how, when the device is worn by a user, the photodiodes receive light after attenuation by tissue of the user.</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 1			
			

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
<p>a protrusion comprising: a convex surface</p>	<p>contains a protrusion at the bottom comprising a convex surface:</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
extending over the interior surface,	<p data-bbox="716 233 1549 266">The protrusion extends over the interior surface, as shown below.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
<p>a plurality of openings in the convex surface extending through the protrusion and aligned with the four photodiodes,</p>	<p>The “convex surface” of the [REDACTED] contains a plurality of openings that extend through the protrusion and are aligned with the four photodiodes (circled in green).</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
<p>each opening defined by an opaque surface, and</p>	<p>Each of the openings is defined by an opaque surface (shown with red dotted line below).</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 1	
<p>a plurality of windows, each of the windows extending across a different one of the openings; and</p>	<p>[REDACTED] contains a plurality of polycarbonate windows, each of the windows extends across a different one of the openings.</p> 
<p>one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate a measurement of the physiological parameter of the user.</p>	<p>The sensor board in [REDACTED] contains a first processor [REDACTED] that [REDACTED] to receive and process the signal received from the photodiodes. The first processor [REDACTED] by a second processor [REDACTED] to calculate both pulse rate and oxygen saturation of the user. Muhsin Decl. ¶ 13.</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 3	
The user-worn device of Claim 1, wherein the windows comprise plastic	<p><i>See Claim 1, supra.</i></p> <p>The window in [REDACTED] are made out of a [REDACTED] plastic. Muhsin Decl. ¶ 20.</p>

Claim 4	
The user-worn device of Claim 1 further comprising:	<i>See Claim 1, supra.</i>
a network interface configured to wirelessly communicate the measurement of the physiological parameter to at least one of: a mobile phone or a computer network;	[REDACTED] includes a wireless communication processor [REDACTED], which uses [REDACTED] to wirelessly communicate the measurement of pulse and oxygen saturation to a user's smart phone. Muhsin Decl. ¶ 15.
a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurement of the physiological parameter;	[REDACTED] includes a touch screen user interface on the face of the product. This touch screen user interface is configured to display the pulse rate ("PR") and oxygen saturation ("SpO2") of the user. Muhsin Decl. ¶ 18.
a storage device configured to at least temporarily store at least the measurement; and	[REDACTED] processor [REDACTED] that stores measurements of physiological parameters, including the user's pulse rate and blood oxygen saturation. Muhsin Decl. ¶¶ 14, 16.

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 4	
<p>a strap configured to position the user-worn device on the user.</p>	<p>[REDACTED] contains a strap to position the device on the user.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 5	
The user-worn device of Claim 1, wherein the opaque surface is configured to reduce light piping.	<p>See Claim 1, <i>supra</i>.</p> <p>As shown in the cross section below, the opaque surface in [REDACTED] prevents light from the LEDs from going directly to the photodiodes without first being attenuated by the skin. Therefore, it is configured to reduce light piping. Muhsin Decl. ¶¶ 14, 16.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 6	
<p>The user-worn device of Claim 1 further comprising: at least one wall extending between the interior surface and the protrusion, wherein at least the interior surface, the wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities.</p>	<p>See Claim 1, <i>supra</i>.</p> <p>As shown in the below cross-section, [REDACTED] has walls that extend between the interior surface and the protrusion and form a cavity (highlighted in yellow) with the interior surface wherein the photodiodes are arranged on the interior surface within the cavities.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 8	
The user-worn device of Claim 1, wherein the physiological parameter comprises oxygen or oxygen saturation.	<i>See Claim 1, supra.</i> One of the physiological parameters measured by [REDACTED] is oxygen saturation (“SpO2”). Muhsin Decl. ¶ 6.
Claim 9	
The user-worn device of Claim 1, wherein the physiological parameter comprises trending information.	<i>See Claim 1, supra.</i> [REDACTED] is capable of displaying trending information for both pulse rate and oxygen saturation. Muhsin Decl. ¶¶ 6, 16.

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 10	
<p>The user-worn device of Claim 1 further comprising a thermistor.</p>	<p>See Claim 1, <i>supra</i>.</p> <p>[REDACTED] contains a thermistor.</p> <p>[REDACTED]</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 11	
<p>The user-worn device of Claim 1, wherein the LEDs and the photodiodes are arranged on a same side of the tissue of the user.</p>	<p><i>See Claim 1, supra.</i></p> <p>In [REDACTED], the LEDs and the photodiodes are both arranged on the inner surface on the same side of the tissue of the user.</p> 
Claim 12	
<p>The user-worn device of Claim 1, wherein the one or more processors are further configured to calculate a bulk measurement responsive to a positioning of the user-worn device.</p>	<p><i>See Claim 1, supra.</i></p> <p>[REDACTED] also has the capability to determine if the sensor is properly positioned [REDACTED]. It does this by processing the signals from the photodiodes and determining a bulk measurement [REDACTED] depending on whether [REDACTED] is properly positioned [REDACTED]. Muhsin Decl. ¶ 17.</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 15	
<p>The user-worn device of Claim 1, wherein the four photodiodes comprise first, second, third and fourth photodiodes and wherein the first photodiode and the second photodiode are arranged on the interior surface across from each other on opposite sides of a central point along a first axis, and the third photodiode and the fourth photodiode are arranged across from each other on opposite sides of the central point along a second axis which is different from the first axis.</p>	<p>See Claim 1, <i>supra</i>.</p> <p>meets this limitation as shown below.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 16	
<p>The user-worn device of Claim 1, wherein the protrusion further comprises one or more extensions.</p>	<p>[REDACTED] protrusion includes an extension.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 17	
<p>The user-worn device of Claim 16, wherein the one or more extensions surround a perimeter of the convex surface of the protrusion.</p>	<p>[REDACTED], the extension surrounds a perimeter of the convex surface of the protrusion.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 18	
<p>The user-worn device of Claim 1, wherein the protrusion further comprises one or more chamfered edges.</p>	<p>[REDACTED] protrusion includes a chamfered edge.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 19	
A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:	[REDACTED] is a user-worn device configured to non-invasively measure an oxygen saturation of a user. Muhsin Decl. ¶¶ 4, 6–7.
a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);	[REDACTED] contains two emitters, each of the emitters comprises at least two LEDs 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;

contains four photodiodes (circled in green below) that are arranged within the user worn device.



EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

When worn by a user, the photodiodes face towards the skin in such a manner to reduce the receipt of light directly from the device's LEDs. In this manner, the photodiodes receive light after attenuation by tissue of the user and accordingly are configured to receive light after attenuation by tissue of the user. Muhsin Decl. ¶¶ 7–9, 11. This is shown in the below cross section of the device, which illustrates how, when the device is worn by a user, the photodiodes receive light after attenuation by tissue of the user.



EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;

contains a protrusion with a convex surface.



contains separate openings extending through the protrusion and positioned over a different one of the four photodiodes (circled in green).



EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

The opaque material is configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue.

The photodiodes receive light after it is attenuated by tissue of the user and accordingly are configured to receive light after attenuation by tissue of the user. Muhsin Decl. ¶¶ 7–9, 11–12. This is shown in the below cross section of the device, which illustrates how, when the device is worn by a user, the photodiodes receive light after attenuation by tissue of the user.



EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


<p>optically transparent material within each of the openings; and</p>	<p>Within each of the openings there is optically transparent material.</p> 
<p>one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.</p>	<p>The sensor board in [REDACTED] contains a first processor [REDACTED] to receive and process the signal received from the photodiodes. The first processor [REDACTED] by a second processor [REDACTED] to calculate the oxygen saturation of the user.</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 20	
<p>The user-worn device of Claim 19 further comprising a thermistor.</p>	<p><i>See Claim 19, supra.</i></p> <p>[REDACTED] contains a thermistor.</p> 
Claim 21	
<p>The user-worn device of Claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user worn device responsive to the temperature signal.</p>	<p>The thermistor sends a signal to the processors to adjust processing of [REDACTED]. The processor receives the temperature signals from the thermistors and, based on the signals, adjusts the calculation of blood oxygen saturation as necessary. Muhsin Decl. ¶ 19</p>


EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 24	
The user-worn device of Claim 19 further comprising:	<i>See Claim 19, supra.</i>
a network interface configured to wirelessly communicate at least the measurements of oxygen saturation to at least one of: a mobile phone or a computer network;	[REDACTED] includes a wireless communication processor [REDACTED], which uses [REDACTED] to wirelessly communicate the measurement of pulse and oxygen saturation to a user's mobile phone.
a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the measurements of oxygen saturation; and	[REDACTED] includes a touch screen user interface on the face of the product. This touch screen user interface is configured to display the oxygen saturation ("SpO2") of the user. Muhsin Decl. ¶ 18.
a memory device configured to at least temporarily store at least the measurements of oxygen saturation.	[REDACTED] processor [REDACTED] that stores measurement of pulse and blood oxygen saturation.

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 25	
<p>The user-worn device of Claim 19, wherein the photodiodes comprise first, second, third and fourth photodiodes and wherein the first photodiode and the second photodiode are arranged across from each other on opposite sides of a central point along a first axis, and the third photodiode and the fourth photodiode are arranged across from each other on opposite sides of the central point along a second axis which is different from the first axis.</p>	<p>See Claim 19, <i>supra</i>. In [REDACTED], the first photodiode and the second photodiode are arranged across from each other on opposite sides of a central point along a first axis, and the third photodiode and the fourth photodiode are arranged across from each other on opposite sides of the central point along a second axis which is different from the first axis.</p> 

Claim 27	
<p>The user-worn device of Claim 19, wherein the optically transparent material is plastic.</p>	<p>See Claim 19, <i>supra</i>.</p> <p>The optically transparent material in [REDACTED] are made out of a [REDACTED] plastic. Muhsin Decl. ¶ 20.</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 28	
<p>A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:</p>	<p>[REDACTED] is a user-worn device configured to non-invasively measure an oxygen saturation of a user. Muhsin Decl. ¶¶ 4, 6–7.</p>
<p>a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;</p>	<p>[REDACTED] contains a first set of light emitting diodes that are configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502
FORMATION


Claim 28	
<p>a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;</p>	<p>[REDACTED] contains a second set of LEDs that are spaced apart from the first set of LEDs, and the second set of LEDs comprises at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 28	
<p>four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;</p>	<p>has four photodiodes (circled in green) that are arranged in a quadrant configuration on an interior surface of the user worn device and are configured to receive light after at least a portion of the light has been attenuated by tissue of the user.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 28	
	<p data-bbox="726 272 1906 451">. In this manner, the photodiodes receive light after attenuation by tissue of the user and accordingly are configured to receive light after attenuation by tissue of the user. Muhsin Decl. ¶¶ 7–9, 11. This is shown in the below cross section of the device, which illustrates how, when the device is worn by a user, the photodiodes receive light after attenuation by tissue of the user.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 28	
a thermistor configured to provide a temperature signal;	<p data-bbox="726 237 1881 302">[REDACTED] contains a thermistor configured to provide a temperature signal. The thermistor sends a signal to the processors [REDACTED]</p> <p data-bbox="726 302 1881 383">[REDACTED] Muhsin Decl. ¶ 19.</p> <div data-bbox="753 396 1902 1016" style="background-color: black; width: 100%; height: 100%;"></div>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 28	
<p>a protrusion arranged above the interior surface, the protrusion comprising: a convex surface;</p>	<p>[REDACTED] contains a protrusion at the bottom that is arranged over the interior surface and comprises a convex surface.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 28	
<p>a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and</p>	<p>The “convex surface” contains a plurality of openings that extend through the protrusion and are aligned with the four photodiodes (circled in green).</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 28	
	<p>Each of the openings is defined by an opaque surface (shown with red dotted line below).</p> <div data-bbox="991 318 1698 1081"></div>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 28

As shown in the cross section below, the opaque surface in

Therefore, it is configured to reduce light piping.



EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 28	
<p>a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;</p>	<p>[REDACTED] contains a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings.</p> 

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502


Claim 28	
<p>at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;</p>	<p>[REDACTED] has opaque walls that extend between the interior surface and the protrusion and form a cavity with the interior surface wherein the photodiodes are arranged on the interior surface within the cavities.</p> 
<p>one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal;</p>	<p>The sensor board in [REDACTED] contains a first processor [REDACTED] to receive and process the signal received from the photodiodes. The first processor [REDACTED] by a second processor [REDACTED] to calculate the oxygen saturation of the user. Muhsin Decl. ¶ 13.</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 28	
a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;	includes a wireless communication processor which uses to wirelessly communicate the measurement of oxygen saturation to a user's mobile phone. Muhsin Decl. ¶ 15.
a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;	includes a touch screen user interface on the face of the product. This touch screen user interface is configured to display the oxygen saturation ("SpO2") of the user. Muhsin Decl. ¶ 18.
a storage device configured to at least temporarily store at least the measurement; and	instrument board includes an instrument processor that stores measurement of blood oxygen saturation. Muhsin Decl. ¶¶ 14, 16.

[REDACTED] EXHIBIT 23: [REDACTED] Claim Charts for U.S. Patent No. 10,912,502
[REDACTED]


Claim 28	
<p>a strap configured to position the user-worn device on the user.</p>	<p>[REDACTED] contains a strap to position the device on the user.</p> 
Claim 29	
<p>The user-worn device of Claim 28, further comprising:</p>	<p><i>See Claim 28, supra.</i></p>
<p>a driver configured to energize the first and second sets of LEDs; and</p>	<p>[REDACTED] contains a driver configured to energize the first and second sets of LEDs. Muhsin Decl. ¶¶ 8–9.</p>


EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 29	
<p>a front-end interface comprising one or more amplifiers and one or more analog to digital converters (ADCs), wherein the front-end interface receives the signals from the photodiodes, the one or more amplifiers amplify the signals and the one or more ADCs convert the signals to digital information, and wherein the processors receive the converted signals.</p>	<p>contains a front-end interface that receives the signals from the photodiodes. The front-end interface contains one or more amplifiers and one or more analog to digital converters. When the front-end interface receives the signal from the photodiodes, the one or more amplifiers amplify the signals and the one or more analog to digital converters convert the signal to digital information, which is then received by the processors. Muhsin Decl. ¶¶ 10, 13.</p>

EXHIBIT 23:

Claim Charts for U.S. Patent No. 10,912,502

Claim 30	
30. The user-worn device of Claim 28, wherein the protrusion further comprises one or more sidewalls extending at least partially around a perimeter of the convex surface.	<p><i>See Claim 28, supra.</i></p> <p>The protrusion includes a sidewall that extends at least partially around the perimeter of the convex surface.</p> 

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EXHIBIT 27

REDACTED

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Investigation No. 337-TA-_____

CONFIDENTIAL DECLARATION OF BILAL MUHSIN

I, Bilal Muhsin, declare as follows:

1. I am the Chief Operating Officer (“COO”) at Masimo Corporation. I have personal knowledge of the facts set forth herein and, if called upon to do so, I could and would testify competently to them.

2. My responsibilities as COO include overseeing operations, clinical research, sales and marketing, medical affairs, information technology, engineering, research and development, regulatory, and quality operations. I first joined Masimo in 1999 as a college intern. After my graduation from San Diego State University with a degree in computer science in 2001, I continued my career at Masimo as an Associate Software Engineer. I moved on from Associate Software Engineer to work at various positions at Masimo, including serving as Masimo’s Vice President of Instruments, Masimo’s Vice President for Engineering, and Masimo’s Executive Vice President for Marketing and Regulatory Affairs. Since May of 2019, I have been the COO of Masimo. In total, I have spent over two decades continuously working at Masimo.

[REDACTED]

3. In my role at Masimo, I have been involved in overseeing the design and development of the [REDACTED] The [REDACTED] relies on decades of

research and development work devoted to measuring physiological parameters of users and builds off wearable sensor technology Masimo has been working on for over a decade.

4. [REDACTED] developed by Masimo and intended for the [REDACTED] Masimo intends to launch the [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

5. [REDACTED]

[REDACTED]

6. [REDACTED] contains numerous features benefiting the user. For example, [REDACTED] tracks a user's physiological parameters, including pulse rate ("PR"), blood oxygen saturation ("SpO₂"), [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] calculates and saves trend data for the various measured physiological parameters.

7. [REDACTED] calculates the physiological parameters via noninvasive spectroscopic analysis. This involves emitting light at various wavelengths towards the tissue [REDACTED] and then using photodetectors to measure the reflected light that has been attenuated by the tissue. The photodetectors output signals responsive to the light received and send the signals to processing circuitry, which calculates the various physiological parameters.

8. [REDACTED] contains two groupings of light emitting diodes (LEDs) [REDACTED] [REDACTED]

[REDACTED]

Each group of LEDs contains

[REDACTED] LEDs that emit light at different wavelengths. [REDACTED] The

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9. [REDACTED] contains a driver to energize the LEDs to emit light. [REDACTED] also contains photodetectors to detect the light reflected from the user after attenuation by their tissue. In total, [REDACTED] has [REDACTED] photodetectors. The below annotated image from a mechanical drawing [REDACTED]

[REDACTED]

CONFIDENTIAL MATERIAL FILED UNDER SEAL REDACTED**[REDACTED]****[REDACTED]****[REDACTED]****[REDACTED]****[REDACTED]****[REDACTED]****[REDACTED]**

11. The photodetectors receive the light emitted from the LEDs and attenuated by the tissue of the user. The photodetectors produce signals responsive to the detected light. However, the photodetectors may also receive light that has not been attenuated by the user's tissue. **[REDACTED]**

[REDACTED]**[REDACTED]**

12. For example, **[REDACTED]** contains a series of openings above each photodetector. The openings have opaque surfaces and contain lateral opaque surfaces.

These openings with their opaque surfaces allow light to reach the photodiodes, but limit the amount of light that occurs from light that is either not produced by the LEDs or not attenuated by the user's tissue, referred to as light piping. As a result, the signals from the photodetectors are substantially free of noise caused by light piping.

13. The intensity of the various wavelengths of light received by the photodetectors creates signals sent to a processor [REDACTED]. The processor, [REDACTED] [REDACTED] is then able to estimate the user's physiological parameters, including blood oxygen content and pulse rate, based on the signals received from the photodetectors. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

14. [REDACTED] includes a processor [REDACTED] [REDACTED] is configured to store measurements of physiological parameters, including the user's blood oxygen saturation and pulse rate.

15. [REDACTED] contains a processor [REDACTED] with wireless [REDACTED] capability allowing the device to communicate with a user's smart phone [REDACTED] and communicate the measurement of the various physiological parameters. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

16. [REDACTED] contains data storage capabilities to allow the storage of measurements for a period of time. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The data storage capabilities also allow for the provision of trend data over time for the measured physiological parameters.

17. [REDACTED] also has the capability [REDACTED]

[REDACTED] It does this by processing the signals from the photodetectors and determining a bulk measurement which will change depending on whether [REDACTED] [REDACTED] positioned properly [REDACTED]

18. [REDACTED] includes a touch-screen user interface. The user interface is configured to provide the user information regarding various measurements [REDACTED]

[REDACTED] For example, the user interface displays the physiological parameters such as blood oxygen saturation and pulse rate collected by the device. [REDACTED] [REDACTED] can calculate and display trend information for the user, for example the oxygen saturation or pulse rate over time.

19. [REDACTED] contains two thermistors. [REDACTED]

[REDACTED] uses the thermistors to measure the temperature. The thermistors output signals indicative of the temperature and sends these signals to a processor to adjust processing [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

20. [REDACTED]

[REDACTED]—contains a series of windows. Masimo is constructing these windows from an optically transparent [REDACTED] plastic material. [REDACTED]

[REDACTED]

[REDACTED]

21. [REDACTED]

[REDACTED] between the windows and the light emitting diodes and separately between the windows and the photodetectors. [REDACTED] spread the light passing through [REDACTED]

22. [REDACTED] housing is hermetically sealed to prevent water from getting into [REDACTED] at certain depths.

23. I have reviewed claim charts relating to [REDACTED] which I understand are being submitted to the ITC as Confidential Exhibits 22-25. Based on my knowledge, these claim charts accurately reflect the design of [REDACTED]

Masimo's Rainbow Sensors

24. Masimo sells a platform of sensors under the rainbow[®] name. These sensors when connected to rainbow[®]-enabled devices, allow clinicians to noninvasively monitor numerous physiological parameters including total hemoglobin, carboxyhemoglobin, methemoglobin, and oxygen content, in addition to oxygen saturation, pulse rate, perfusion index, and pleth variability index. Masimo includes the rainbow[®] sensor technology in both single-patient use sensors and as reusable sensors, and the sensors are available in various sizes for adult patients, adolescents, and neonates.

25. Masimo sells the following rainbow[®] sensors, which may be available in various configurations (for example different sensor lengths) and for different patient populations (neonates, pediatrics, and adult):

- RD rainbow[®] Set-2
- rainbow[®] R1
- rainbow[®] R25
- rainbow[®] R20
- rainbow[®] DCI SC 200

- rainbow[®] DCI SC 400
- rainbow[®] DCI SC 1000
- rainbow[®] DCI mini SC-200
- rainbow[®] DCI mini SC-400
- rainbow[®] DCI mini SC-1000
- rainbow[®] Super DCI-mini SC-200
- rainbow[®] Super DCI mini SC-400
- rainbow[®] Super DCI mini SC-1000
- rainbow[®] DCI
- rainbow[®] DCI-dc
- RD rainbow[®] 8 λ SpCO Adhesive Sensor
- LNCS-II[™] rainbow[®] DCI[®] 8λ SpHb
- LNCS-II[™] rainbow[®] DCIP[®] 8λ SpHb
- LNCS-II[™] rainbow[®] DCI[®] 8λ SpCO
- LNCS-II[™] rainbow[®] DCIP[®] 8λ SpCO

26. Based on my work at Masimo, I have knowledge regarding the development of and technical specifications of the rainbow[®] sensors.

27. The research and development and manufacturing of the rainbow[®] sensors involved and still involves significant work in the United States. When originally sold, the rainbow[®] sensors contained LEDs, [REDACTED]

[REDACTED] For some of the specific LEDs, which were essential to the rainbow[®] sensor platform, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED] This led to the acquisition of the Masimo Semiconductor facility in Hudson, New Hampshire. The Hudson, New Hampshire facility is approximately 86,500 square feet and Masimo uses a portion of the facility to manufacture advanced LEDs and other advanced component-level technologies.

28. Although the various rainbow[®] sensors may have different configurations and are capable of measuring different parameters, [REDACTED]

[REDACTED] [REDACTED] For example, the emitter package might include a different number of LEDs depending on functionality, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

CONFIDENTIAL MATERIAL FILED UNDER SEAL REDACTED

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

CONFIDENTIAL MATERIAL FILED UNDER SEAL REDACTED

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

31. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1 [REDACTED]

[REDACTED]

CONFIDENTIAL MATERIAL FILED UNDER SEAL REDACTED

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

32. [REDACTED]

[REDACTED]

[REDACTED]

CONFIDENTIAL MATERIAL FILED UNDER SEAL REDACTED

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

34.

[REDACTED]

[REDACTED]

[REDACTED]

CONFIDENTIAL MATERIAL FILED UNDER SEAL REDACTED

[REDACTED]

35.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

36. [REDACTED]

[REDACTED]

[REDACTED]

37. In the rainbow[®] sensors, [REDACTED]

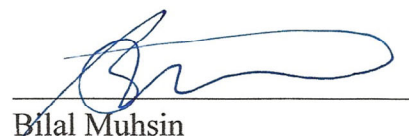
[REDACTED]

[REDACTED]

38. I have reviewed the claim charts in Confidential Exhibit 26, which contain information related to rainbow[®] sensors. I believe that the claim charts are representative of the relevant functionality and physical structure of the vast majority of rainbow[®] sensors currently sold by Masimo and previously sold by Masimo.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on June 28, 2021,


Bilal Muhsin

Appx2937

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**In the Matter of Certain Light-Based
Physiological Measurement Devices and
Components Thereof**

Investigation No. 337-TA-_____

**FIRST AMENDED COMPLAINT UNDER SECTION 337 OF
THE TARIFF ACT OF 1930, AS AMENDED**

Complainants:

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LIST OF EXHIBITS

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1	Certified Copy of U.S. Patent No. 10,912,501
2	Copy of U.S. Patent No. 10,912,502
3	Certified Copy of U.S. Patent No. 10,945,648
4	Certified Copy of U.S. Patent No. 10,687,745
5	Certified Copy of U.S. Patent No. 7,761,127
6	Certified Assignment Documents for U.S. Patent No. 10,912,501
7	Certified Assignment Documents for U.S. Patent No. 10,912,502
8	Certified Assignment Documents for U.S. Patent No. 10,945,648
9	Certified Assignment Documents for U.S. Patent No. 10,687,745
10	Certified Assignment Documents for U.S. Patent No. 7,761,127
11	CONFIDENTIAL EXHIBIT: Amended and Restated Cross-Licensing Agreement between Masimo Laboratories and Masimo Corporation Effective January 1, 2007
12	Listing of All Foreign Patents and All Foreign Patent Applications Corresponding to Asserted Patents
13	Representative Photos of Representative Apple Watch Series 6 (Model No. 109.627 shown)
14	Product Literature Regarding the Apple Watch Series 6
15	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Claims of the '501 Patent to an Apple Watch Series 6
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20	CONFIDENTIAL EXHIBIT Drawings, Photographs, or Other Visual Representations of Masimo's rainbow [®] Sensors
21	CONFIDENTIAL EXHIBIT: Drawings, Photographs, or Other Visual Representations of Masimo's Confidential Domestic Industry Product
22	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '501 Patent to Masimo's Domestic Industry Product
23	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '502 Patent to Masimo's Domestic Industry Product
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26	CONFIDENTIAL EXHIBIT: Claim Chart Comparing Exemplary Claims of the '127 Patent to Masimo's Domestic Industry Products
27	CONFIDENTIAL EXHIBIT: Confidential Declaration of Bilal Muhsin
28	CONFIDENTIAL EXHIBIT: Confidential Declaration of Micah Young
29	September 15, 2020 Press Release
30	CONFIDENTIAL EXHIBIT: Invoice dated April 19, 2021
31	Photographs of Product Packaging of the Apple Watch Series 6
32	January 28, 2021 Apple 10K Filing with SEC
33	Fowler, Geoffrey, "The new Apple Watch says my lungs may be sick. Or perfect. It can't decide." <i>Washington Post</i> , September 23, 2020.
34	Masimo Form 10-K, dated February 23, 2021
35	"The Apple Watch's blood oxygen sensor is less accurate than you think"
36	"Can the Apple Watch Series 6 Keep the Doctor Away?"
37	"Apple Watch Series 6 review – Minute Improvements"
38	"The New Apple Watch 6 May Have a Problem. Oddly Enough, That's OK"
39	"Apple Watch Series 6 and SE Review – Watch Out for the Upsell"
40	Provisional Application No. 60/367,428

LIST OF APPENDICES

Appendix	Description
A	File History for U.S. Patent No. 10,912,501
B	Relevant Technical References Cited in File History for U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648
C	File History for U.S. Patent No. 10,912,502
D	File History for U.S. Patent No. 10,945,648
E	Certified File History for U.S. Patent No. 10,687,745
F	Relevant Technical References Cited in File History for U.S. Patent No. 10,687,745
G	Certified File History for U.S. Patent No. 7,761,127
H	Relevant Technical References Cited in File History for U.S. Patent No. 7,761,127

I. INTRODUCTION

1. Masimo Corporation and Cercacor Laboratories, Inc. (collectively, “Masimo” or “Complainants”) request that the United States International Trade Commission (“Commission”) institute an investigation into violations of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”) committed by Respondent Apple Inc. (“Apple”) (“Apple” or “Respondent”).

2. This First Amended Complaint (“Complaint”) is based on Respondent’s unlawful and unauthorized importation into the United States, sale for importation, and/or sale within the United States after importation of certain light-based physiological measurement devices and components thereof. Respondent’s products, including, but not limited to, the “Apple Watch Series 6,” or “Series 6” (“Accused Products”) infringe at least one claim of U.S. Patent No. 10,912,501, titled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” (“the ’501 Patent”), U.S. Patent No. 10,912,502, titled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” (“the ’502 Patent”), U.S. Patent No. 10,945,648, titled “User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User,” (“the ’648 Patent”), U.S. Patent No. 10,687,745, titled “Physiological Measurement Devices, Systems, and Methods,” (“the ’745 Patent”), and U.S. Patent No. 7,761,127, titled “Multiple Wavelength Sensor Substrate,” (“the ’127 Patent”) (collectively, “the Asserted Patents”), either literally or under the doctrine of equivalents.

3. The Accused Products directly infringe and/or induce the infringement of, literally or under the doctrine of equivalents, at least the following claims (collectively, “the Asserted Claims”) of the Asserted Patents:

<u>U.S. Patent</u>	<u>Asserted Claims¹</u>
'501 Patent	1-9, 11-18, 19-25 and 26-30
'502 Patent	1-2, 4-6, 8-12, 14-18, 19-22, 24-26, and 28-30
'648 Patent	1-5, 6-17, 19, and 20-30
'745 Patent	1-6, 8-9, 11, 14, 20-24, and 26-27
'127 Patent	7-9

Further discovery may reveal that Respondent infringes additional claims.

4. Certified copies of the '501 Patent, '502 Patent, '648 Patent, '745 Patent, and '127 Patent are attached hereto as **Exhibits 1, 2, 3, 4, and 5**, respectively. Masimo Corp. owns by assignment the entire right, title, and interest in and to the '501 Patent, '502 Patent, '648 Patent, and '745 Patent (collectively, “the Masimo Patents”). Certified copies of the recorded assignments of the Masimo Patents are attached hereto as **Exhibits 6, 7, 8, and 9**, respectively. Masimo Corp. exclusively licenses certain rights to the Masimo Patents to Cercacor. A copy of the Amended and Re-Stated Cross-Licensing Agreement between Masimo Corp. and Cercacor (formerly known as Masimo Laboratories) granting the license to Cercacor is attached hereto as **Confidential Exhibit 11**. Cercacor owns by assignment the entire right, title, and interest in and to the '127 Patent (“the Cercacor Patent”). Certified copies of the recorded assignment of the Cercacor Patent are attached hereto as **Exhibit 9**. Masimo is a licensee of certain exclusive rights to the Cercacor Patents, as reflected in **Confidential Exhibit 11**.

5. Respondent’s activities with respect to the importation into the United States, the

¹ Independent claims are noted in **BOLD**.

sale for importation into the United States, and/or the sale within the United States after importation of certain light-based physiological measurement devices and components thereof, described more fully *infra*, are unlawful under 19 U.S.C. § 1337(a)(1)(B)(i) in that they constitute infringement of the valid and enforceable Asserted Patents.

6. As required by Section 337(a)(2) and defined by Section 337(a)(3), industries exist in the United States relating to articles covered by the Asserted Patents or alternatively such industries relating to articles protected by the Asserted Patents are in the process of being established.

7. Complainants seek relief from the Commission in the form of a permanent limited exclusion order, pursuant to Section 337(d), excluding from entry into the United States the Accused Products that infringe one or more claims of the Asserted Patents. Complainants also seek a permanent cease and desist order, pursuant to Section 337(f), directing Respondent to immediately cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, distributing, offering for sale, selling, or using in the United States the certain light-based physiological measurement devices and components thereof that infringe one or more claims of the Asserted Patents.

8. Complainants further seek as relief a bond, for the 60-day Presidential review period pursuant to Section 337(j), for the importation of the certain light-based physiological measurement devices and components thereof that infringe one or more claims of the Asserted Patents.

II. COMPLAINANTS

9. Complainant Masimo Corporation is a Delaware corporation having its principal place of business at 52 Discovery, Irvine, California 92618. Masimo owns the Masimo Patents and has certain exclusive rights to the Cercacor Patent. (See Exhibits 1-4, 6-9, Confidential

Exhibit 11). Complainant Cercacor is a Delaware corporation having its principal place of business at 15750 Alton Pkwy, Irvine, CA 92618. Cercacor is the owner of the Cercacor Patent and has certain exclusive rights to the Masimo Patents. (See **Exhibits 5 and 10, Confidential Exhibit 11**).

10. Masimo is a global medical technology company that has revolutionized non-invasive monitoring of physiological parameters, such as pulse rate, arterial oxygen saturation and many others. These innovations have been repeatedly recognized by Federal courts. See *Mallinckrodt, Inc. v. Masimo Corp.*, Case No. 2:00-CV-06506 (C.D. Cal. Apr. 5, 2004), ECF No. 588; *Mallinckrodt, Inc. v. Masimo Corp.*, Case No. 2:00-CV-06506 (C.D. Cal. July 12, 2004), ECF No. 622; *Mallinckrodt, Inc. v. Masimo Corp.*, Case No. 2:00-CV-06506 (C.D. Cal. Aug. 4, 2004), ECF No. 632, *aff'd in part and rev'd in part*, 147 F. App'x 158 (Fed. Cir. 2005); *Mallinckrodt, Inc. v. Masimo Corp.*, 147 F. App'x 158 (Fed. Cir. 2005); *Masimo Corp. v. Philips Elec. N. Am. Corp.*, Case No. 1:09-CV-00080 (D. Del. Oct. 17, 2014), ECF No. 919; *Masimo Corp. v. Philips Elec. N. Am. Corp.*, Case No. 1:09-CV-00080 (D. Del. May 18, 2015), ECF No. 997; *Masimo Corp. v. Philips Elec. N. Am. Corp.*, Case No. 1:09-CV-00080 (D. Del. May 18, 2015), ECF No. 998.

11. Masimo develops, manufactures, and markets a variety of noninvasive patient monitoring technologies and hospital automation solutions as part of its mission to improve patient outcomes and reduce the cost of patient care. Masimo's patient monitoring solutions are systems that generally incorporate a monitor or circuit board, proprietary single-patient use or reusable sensors, software and/or cables. Masimo primarily sells its products to professional caregivers, such as hospitals, emergency medical service providers, home care providers, physician offices,

veterinarians, long term care facilities and also to consumers, through its direct sales force, online, distributors, and original equipment manufacturer (OEM) partners.

12. Masimo has rapidly expanded its workforce despite the COVID-19 Pandemic. As of December 28, 2019, Masimo had approximately 1,600 full-time employees and approximately 3,700 dedicated contract personnel worldwide. **Exhibit 34** (Masimo Form 10k) at 34. By January 2, 2021, Masimo had grown to 2,000 full-time employees and approximately 4,200 dedicated contract personnel worldwide.

13. Masimo's core business is referred to as Masimo SET[®] pulse oximetry. Pulse oximetry allows for the noninvasive measurement of the oxygen saturation level of arterial blood, which delivers oxygen to the body's tissues. Pulse oximetry also allows for the measurement of pulse rate. "SET" refers to Masimo's Signal Extraction Technology, a technology invented by Masimo that, for the first time, allowed pulse oximeters to provide accurate measurements of oxygen saturation even during patient motion and low perfusion (i.e., decreased arterial blood flow) conditions.

14. Over the years, Masimo's product offerings have expanded significantly to also include rainbow[®] Pulse CO-Oximetry, with its unique ability to allow for real-time non-invasive monitoring of additional physiological measurements, including carboxyhemoglobin (SpCO[®]), methemoglobin (SpMet[®]), total hemoglobin concentration (SpHb[®]) and fractional arterial oxygen saturation (SpfO2[™]). Rainbow[®] Pulse CO-oximetry also has the ability to measure pulse rate, perfusion index (Pi), Pleth Variability Index (PVi[®]) and respiration rate from the pleth (RRp[®]). The rainbow SET[®] platform also allows for the calculation of Oxygen Content (SpOC[™]) and Oxygen Reserve Index (ORi[™]).

15. Masimo's current technology offerings also include remote patient monitoring, connectivity, and hospital automation solutions, including Masimo Patient SafetyNet™, Masimo Patient SafetyNet™ Surveillance, Replica™, Iris®, MyView®, UniView™ and Trace™. Masimo's technologies are supported by a substantial intellectual property portfolio.

16. Masimo invests significantly in its research and development efforts, and currently spends about 10% of its sales revenue on research and development activities. For the year ending January 2, 2021, Masimo spent approximately \$118,689,000 for research and development activities. **Exhibit 34** (Masimo Form 10k) at 66. The majority of these activities take place in the United States. **Exhibit 34** (Masimo Form 10k) at 62. As a result of these efforts, Masimo has been awarded numerous patents in the United States and around the world. As of January 2, 2021, Masimo had approximately 800 issued patents and approximately 500 pending applications in the U.S., Europe, Japan, Australia, Canada and other countries throughout the world. **Exhibit 34** (Masimo Form 10k) at 32.

17. Masimo owns two facilities in Irvine, California, with combined square footage of approximately 314,400, housing its corporate headquarters and the majority of its U.S. research and development activities. Masimo also owns approximately 86,500 square feet of property in Hudson, New Hampshire, which is used to develop and manufacture advanced light emitting diodes and other advanced component-level technologies, as well as warehousing and administrative operations.

18. Masimo also leases and occupies approximately 105,800 square feet of additional building space in Irvine, California for product manufacturing and warehousing. Masimo also leases or owns an additional 61,000 square feet at various locations throughout the United States, that provide centers for distribution of Masimo's products directly to its customers, and is in the

[REDACTED]

process of establishing distribution centers throughout the United States, [REDACTED]

[REDACTED].

19. Complainant Cercacor is a health and wellness innovator based in Irvine, California. In 1998, Masimo spun certain technology off into a new company, Masimo Laboratories, Inc. or “Masimo Labs,” to further research and develop the technologies. The name of the company was later changed to “Cercacor.” Cercacor and Masimo have a license agreement between them to facilitate collaboration between the companies.

20. Like Masimo, Cercacor is an innovator of non-invasive monitoring technologies. Cercacor is on the frontline of understanding how measuring, tracking, and analyzing physiological parameters can impact pre-diabetic and diabetic patients, endurance sports training and performance, and overall health and wellness. Cercacor continued the development that started at Masimo on numerous non-invasive parameters. Leading hospitals around the world use Cercacor technology licensed to Masimo and sold under the name Masimo rainbow SET[®]. This technology was the first, and remains the only, noninvasive monitoring technology that can measure carbon monoxide, methemoglobin, and total hemoglobin in the blood.

III. PROPOSED RESPONDENT

21. Respondent Apple Inc. (“Apple”) is a California corporation having a principal place of business at One Apple Park Way, Cupertino, California 95014. Apple unlawfully sells for importation, imports, and/or sells after importation into the United States certain light-based physiological measurement devices and components thereof, including the Apple Watch Series 6, that infringe the ’501 Patent, the ’502 Patent, the ’648 Patent, the ’745 Patent, and the ’127 Patent, either literally or under the doctrine of equivalents.

22. Apple is in the business of designing, manufacturing, and marketing smartphones, personal computers, tablets, wearables, and accessories, and sells a variety of related services.

Apple's wearables include certain light-based physiological measurement devices and components thereof, including the Apple Watch Series 6.

IV. PRODUCTS AND TECHNOLOGY AT ISSUE

A. Complainants' Technology

23. Products that practice one or more claims of the Asserted Patents—including the Accused Products and Masimo's Domestic Industry products—are light-based physiological measurement devices and components thereof. These physiological measurement devices typically rely on light that is transmitted through the body tissue. The received light, that has been attenuated by the various components of the body tissue, including the pulsing arterial blood, is known in the industry as a photoplethysmography or "PPG." The transmission and receipt of this light is typically accomplished through a sensor that is applied to a body part such as a finger, arm, toes, forehead or ear.

24. Before Masimo, non-invasive measurements from the PPG were plagued by unreliability, often when the measurement was needed most, due to the person moving or having low peripheral blood flow (known as "low perfusion"). The industry had essentially given up on solving these problems, concluding they were largely unsolvable. In the medical context, clinicians had to live with the results—patient monitors gave excessive false alarms, froze their measurements for prolonged periods of time despite potential changes in the physiological parameter (e.g., oxygen saturation or pulse rate), delayed notification of alarms due to long averaging times of sensor data, produced inaccurate measurements, or were unable to obtain data on the most critical patients and babies who cannot be instructed to stay still. Masimo's pioneering Masimo SET[®] technology, solves this problem and dramatically improved the reliability of monitoring and reporting physiological signals derived from the PPG.

25. Following its initial success with Masimo SET® technology, Masimo invested heavily in developing additional breakthrough measurement technologies, such as non-invasively measuring total hemoglobin, carboxyhemoglobin, and methemoglobin. Masimo has continued to innovate, succeeding where others have consistently failed. Masimo was the first, and remains the only, company delivering these game-changing technologies to hospitals in the United States. Use of Masimo's technology in the clinical setting has been proven to reduce blindness in premature infants, detect congenital heart disease in infants, save lives on the general care floor and post-surgery, and improve transfusion management, while also saving substantial money for the hospitals providing care.

26. Masimo's investment in its technology and research and development has included significant investments in wrist-worn devices for measurements of physiological parameters. Masimo's patent filings as early as 2002 disclose wrist-worn devices for measuring physiological parameters that wirelessly connected to monitors. *See Exhibit 40* (Provisional Application No. 60/367,428 filed on March 25, 2002).

27. One of Masimo's commercially marketed wrist-worn device for measuring physiological parameters, the Radius PPG, was cleared by the FDA in May of 2019. The Radius PPG eliminated the need for a cabled connection to a pulse oximetry monitor, allowing patients to move freely and comfortably while still being continuously monitored reliably and accurately. The device communicated with monitors via a wireless connection allowing patients to benefit from mobility.

28. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

29. Given its success selling medical-grade devices for non-invasively measuring physiological parameters, Complainants decided to leverage these clinical grade products for sale directly to consumers where allowable. Masimo noticed that there has been many devices sold to consumers purporting to provide physiological measurements, but could identify none that provided clinical grade measurement. The devices available to consumers were more like toys. In 2013, Masimo first began selling its pulse oximetry products to the consumer market. After Masimo began selling directly to consumers, it also increased its investment in direct-to-consumer advertising, including being a premium sponsor of the BNP Paribas Open Tennis Tournament in Palm Springs, CA.

30. Notably, despite the acute awareness of pulse oximetry created by the COVID-19 pandemic, the large multitude of so-called pulse oximeters offered to consumers are prohibited for medical purposes. Unfortunately, the consumers do not recognize this, which puts their health at risk.

31. The Asserted Patents claim devices and/or components of devices used in the non-invasive measurement of physiological parameters such as oxygen saturation. For example, the four Masimo Patents claim devices containing multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. The devices are configured in specific ways which improve the successful detection of the signal while minimizing the effects of light-piping. The Cercacor Patent also claims novel technologies assisting in the non-invasive measurement of physiological parameters. The '127 Patent claims a

sensor using a thermal mass within a substrate to measure and account for effects on measurements from temperature changes.

B. Apple's Copying of Complainants' Technology

32. In 2013, Apple contacted Masimo and asked to meet regarding a potential collaboration. Apple told Masimo that Apple would like to understand more about Masimo's technology to potentially integrate that technology into Apple's products. Apple and Masimo later entered into a confidentiality agreement, and Masimo's management met with Apple. The meetings included confidential discussions of Masimo's technology. After what seemed to Masimo to have been productive meetings, Apple quickly began hiring Masimo's employees, including engineers and key management.

33. Masimo employed Michael O'Reilly as its Chief Medical Officer and Executive Vice President for Medical Affairs beginning in January 2008. As part of the Masimo executive team, O'Reilly was privy to extremely sensitive information, including information about mobile medical products and applications, wellness applications, clinical data gathering and analytics, and other technology of Masimo. Upon information and belief, Apple employed O'Reilly in July 2013, shortly after the meetings with Masimo, to assist in wellness and mobile applications that include non-invasive measurement of physiological parameters. Not long after, by December of 2013, O'Reilly was already meeting with the FDA on behalf of Apple to discuss medical applications and discuss medical products that non-invasively measures blood constituents.

34. Apple systematically recruited other key Masimo personnel, such as Marcelo Lamago (a named inventor on many of the Asserted Patents), who was the former Chief Technical Officer of Cercacor and a former Research Scientist at Masimo. Lamago was a Masimo employee during 2000-2001 and 2003-2006, and the Cercacor Chief Technical Officer during 2006-2014.

35. Lamego had unfettered access to Complainants' technical information. He was trained and mentored at Masimo by the most skilled engineers and scientists, and was taught about the keys to effective non-invasive monitoring, something he was not involved in prior to Masimo. Masimo engineers and scientists including, among others, Ammar Al-Ali, Mohamed Diab, and Walter Weber, exposed Lamego to all of Masimo's technology on non-invasive monitoring. The Masimo engineers, including Al-Ali, Diab, and Weber, were Masimo employees at all relevant times. Lamego also had access to and learned guarded secrets regarding Complainants' mobile medical products, including key technology and advance plans for future products.

36. When Lamego left Cercacor, he assured Complainants that he would not violate his agreements with Complainants and volunteered that he would not work on technology similar to Complainants' technology. On January 24, 2014, Complainants sent a letter to Apple explaining that Lamego possessed Complainants' confidential proprietary information and warning Apple to respect Complainants' rights in such information. The letter stated, "we trust that Apple will employ Mr. Lamego in an area that does not involved healthcare technology, including mobile health applications and the measurement of physiological information." The letter also asked that "Apple refrain from inducing Mr. Lamego to take actions that would violate the Agreement while he performs services for Apple" and asked Apple to "direct Mr. Lamego to honor his obligations to all of his prior employers." Based on Complainants' conversations with Lamego, Complainants' letter to Apple, and Complainants' confidentiality agreement with Apple, Complainants' reasonably believed that Lamego would not use or disclose Complainants' confidential information and that Apple would not induce Lamego to do so or itself use Complainants' confidential information.

37. Unbeknownst to Complainants at the time, it now appears that, shortly after joining Apple in January 2014, Lamego began pursuing on behalf of Apple numerous patent applications directed toward technologies he worked on at Complainants, and with which he had no prior experience or knowledge.

38. Apple announced the first version of its watch in September 2014 and began shipping its watch in April 2015. On information and belief, Apple began incorporating Masimo's technology in later versions of its watch. Ultimately with the launch of the Apple Watch Series 6 in September 2020, Apple for the first time purported to have incorporated the ability to measure blood oxygen saturation (pulse oximetry) into its watches—technology, which as described in more detail below, infringes the Asserted Claims. Unfortunately for U.S. consumers, the Apple Watch Series 6 differs from Masimo's medical grade technology in that Apple's Accused Products do not reliably measure blood oxygen concentrations, as described in **Exhibits 33 and 35-39**.

C. The Accused Products

39. Pursuant to 19 C.F.R. § 210.12(a)(12), the category of the Accused Products may be plainly described as wearable electronic devices with light-based pulse oximetry functionality, including various devices made by Apple, including, but not limited to, various models of the Apple Watch Series 6. The Apple Watch Series 6 is an electronic smartwatch, which purportedly includes pulse oximetry functionality. Relevant here, the Accused Products contain LEDs, photodiodes, and other features within the scope of the Masimo Patents to measure the oxygen saturation of the user. The Accused Products also contain the thermal mass technology claimed in the '127 Patent. The infringing products—including their associated systems, and components thereof—are further described in **Exhibits 15, 16, 17, 18, and 19**, which include claim charts comparing the Asserted Claims to the Apple Watch Series 6. The Apple Watch Series 6 either

infringes these claims upon importation or Apple induces consumers to infringe these claims through its sale of the Apple Watch Series 6 and its recommendation, encouragement, and/or instruction to users to use the Apple Watch Series 6 in connection with an iPhone.

40. The Apple Watch Series 6 is imported into and sold within the United States by or on behalf of Apple. On information and belief, commercially significant volumes of infringing products are maintained in inventory by Apple in the United States.

41. The identification of exemplary Accused Products is intended purely for illustration and is not intended to limit the scope of the investigation. Any remedy should extend to all present and future infringing products of Apple, regardless of model number, name, or type of product.

V. THE ASSERTED PATENTS

A. U.S. Patent No. 10,912,501

1. Identification of the Patent and Ownership by Masimo Corporation

42. Masimo Corporation owns by assignment the entire right, title, and interest in the '501 Patent, entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," which issued on February 9, 2021. **Exhibit 1.** The '501 Patent issued from U.S. Patent Application Serial No. 17/031,356, filed on September 24, 2020. The '501 Patent is a continuation of U.S. Patent Application No. 16/834,538, filed March 30, 2020, which is a continuation of U.S. Patent Application No. 16/725,292, filed December 23, 2019, which is a continuation of U.S. Patent Application No. 16/534,949, filed August 7, 2019, which is a continuation of U.S. Patent Application No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. Patent Application No. 16/261,326, filed January 29, 2019, which is a continuation of U.S. Patent Application No. 16/212,537, filed December 6, 2018, which is a continuation of U.S. Patent Application No. 14/981,290 filed December 28, 2015, which is a continuation of U.S. Patent

Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,523 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. A certificate of correction issued on the '501 Patent on April 6, 2021. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the '501 Patent is August 25, 2028.

43. The inventors of the '501 Patent, Jeroen Poeze, Marcelo Lamego, Sean Merritt, Cristiano Dalvi, Hung Vo, Johannes Bruinsma, Ferdyan Lesmana, Massi Joe E. Kiani, and Greg Olsen, assigned to Masimo Laboratories, Inc. the entire right, title, and interest throughout the world in, to and under said improvements in the invention described and claimed in U.S. Patent Application No. 12/534,827 and all divisions and continuations thereof, which includes the '501 Patent. **Exhibit 9.** On August 2, 2010, Masimo Laboratories Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 9.** On July 29, 2019, Cercacor assigned to Masimo Corporation, the entire right, title and interest to U.S. Application No. 16/212537 and all continuations thereof, which includes the '501 Patent. **Exhibit 9.** Cercacor is the licensee of certain exclusive rights to the '501 Patent. **Confidential Exhibit 17.** The '501 Patent is valid, enforceable, and is currently in full force and effect.

44. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the prosecution history of the '501 Patent²; and 2) an electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices A and B, respectively.

2. Foreign Counterparts to the '501 Patent

² Due to USPTO errors, Complainants submitted certificates of correction to correct typographical errors in U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648 as originally issued. Complainants have not yet received a certified copy of U.S. Patent No. 10,912,502 with the certificate of correction attached and have not yet received the certified copies of the prosecution histories which contain the information related to the certificates of correction for U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648. Accordingly, Complainants are submitting uncertified copies of the prosecution histories of U.S. Patent Nos. 10,912,501, 10,912,502, and 10,945,648, and an uncertified copy of U.S. Patent No. 10,912,502, and will submit certified copies once received.

45. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the '501 Patent. **Exhibit 12.** No other foreign patents or patent applications corresponding to the '501 Patent are known to Masimo Corporation.

3. Non-Technical Description of the '501 Patent

46. The '501 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The '501 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The '501 Patent also includes limitations to novel arrangements of light sources and photodetectors. The '501 Patent also contains limitations to processors, network devices, and user interfaces, allowing the device to be easily used by consumers.

47. In sum, the invention of the '501 Patent provides a novel combination of features allowing for the measurement of a user's physiological parameters. [REDACTED]

[REDACTED].

48. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '501 Patent.

B. U.S. Patent No. 10,912,502

1. Identification of the Patent and Ownership by Masimo Corporation

49. Masimo Corporation owns by assignment the entire right, title, and interest in the '502 Patent, entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," which issued on February 9, 2021. **Exhibit 2.** The '502 Patent issued from U.S. Patent Application Serial No. 17/031,407, filed on September 24, 2020. The '502 Patent is a continuation of a continuation of U.S. Patent Application No. 16/834,538, filed March 30, 2020, which is a continuation of U.S. Patent Application No. 16/725,292, filed December 23, 2019, which is a continuation of U.S. Patent Application No. 16/534,949, filed August 7, 2019, which is a continuation of U.S. Patent Application No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. Patent Application No. 16/261,326, filed January 29, 2019, which is a continuation of U.S. Patent Application No. 16/212,537, filed December 6, 2018, which is a continuation of U.S. Patent Application No. 14/981,290 filed December 28, 2015, which is a continuation of U.S. Patent Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25,

2008. U.S. Patent Application No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,523 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. On May 25, 2021, the PTO approved a certification of correction for the '502 patent and the certificate of correction issued on July 6, 2021. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the '502 Patent is August 25, 2028.

50. The inventors of the '502 Patent, Jeroen Poeze, Marcelo Lamego, Sean Merritt, Cristiano Dalvi, Hung Vo, Johannes Bruinsma, Ferdyan Lesmana, Massi Joe E. Kiani, and Greg Olsen, assigned to Masimo Laboratories, Inc. the entire right, title, and interest throughout the world in, to and under said improvements in the invention described and claimed in U.S. Patent Application No. 12/534,827 and all divisions and continuations thereof, which includes the '502 Patent. **Exhibit 7.** On August 2, 2010, Masimo Laboratories Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 7.** On July 29, 2019, Cercacor assigned to Masimo Corporation, the entire right, title and interest to U.S. Application No. 16/212537 and all continuations thereof, which includes the '502 Patent. **Exhibit 7.** Cercacor is the licensee of certain exclusive rights to

the '502 Patent. **Confidential Exhibit 11.** The '502 Patent is valid, enforceable, and is currently in full force and effect.

51. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the prosecution history of the '502 Patent; and 2) a electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices C and B, respectively. Because the '501 Patent, '502 Patent, and '648 Patent are related, there is a substantial overlap of the patents and applicable pages of each technical reference mentioned in the prosecution histories and the copies are provided together in Appendix B.

2. Foreign Counterparts to the '502 Patent

52. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the '502 Patent. **Exhibit 12.** No other foreign patents or patent applications corresponding to the '502 Patent are known to Masimo Corporation.

3. Non-Technical Description of the '502 Patent

53. Like the '501 Patent, the '502 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The '502 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The '502 Patent also

[REDACTED]

includes limitations to novel arrangements of light sources and photodetectors. The '502 Patent also contains limitations to processors, network devices, and user interfaces, allowing the device to be easily used by consumers.

54. In sum, the invention of the '502 Patent provides a novel combination of features allowing for the measurement of a user's physiological parameters. [REDACTED]

[REDACTED]

55. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '502 Patent.

C. U.S. Patent No. 10,945,648

1. Identification of the Patent and Ownership by Masimo Corporation

56. Masimo Corporation owns by assignment the entire right, title, and interest in the '648 Patent, entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," which issued on March 16, 2021. (See **Exhibit 3**). The '648 Patent issued from U.S. Patent Application Serial No. 17/031,316, filed on September 24, 2020. The '648 Patent is a continuation of is a continuation of U.S. Patent Application No. 16/834,538, filed March 30, 2020, which is a continuation of U.S. Patent Application No. 16/725,292, filed December 23, 2019, which is a continuation of U.S. Patent Application No. 16/534,949, filed August 7, 2019, which is a continuation of U.S. Patent Application No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. Patent Application No. 16/261,326, filed January 29, 2019, which is a continuation of U.S. Patent Application No. 16/212,537, filed December 6, 2018, which is a continuation of U.S. Patent Application No. 14/981,290 filed December 28, 2015, which is a

continuation of U.S. Patent Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,523 filed July 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed August 4, 2008, 61/086,108 filed August 4, 2008, 61/086,063 filed August 4, 2008, 61/086,057 filed August 4, 2008, 61/078,228 filed July 3, 2008, 61/078,207 filed July 3, 2008, and 61/091,732 filed August 25, 2008. U.S. Patent Application No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design Patent Application Nos. 29/323,409 filed August 25, 2008 and 29/323,408 filed August 25, 2008. A certificate of correction issued on the '648 Patent on April 20, 2021. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the '648 Patent is August 25, 2028.

57. The inventors of the '648 Patent, Jeroen Poeze, Marcelo Lamago, Sean Merritt, Cristiano Dalvi, Hung Vo, Johannes Bruinsma, Ferdyan Lesmana, Massi Joe E. Kiani, and Greg Olsen, assigned to Masimo Laboratories, Inc. the entire right, title, and interest throughout the world in, to and under said improvements in the invention described and claimed in U.S. Patent Application No. 12/534,827 and all divisions and continuations thereof, which includes the '648 Patent. **Exhibit 8.** On August 2, 2010, Masimo Laboratories Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 8.** On July 29, 2019, Cercacor assigned to Masimo Corporation, the entire right, title and interest to U.S. Application No. 16/212537 and all continuations thereof, which includes the '648 Patent. **Exhibit 8.** Cercacor is the licensee of certain exclusive rights to the '648 Patent. **Confidential Exhibit 11.** The '648 Patent is valid, enforceable, and is currently in full force and effect.

58. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the prosecution history of the '648 Patent; and 2) a electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices D and B, respectively. Because the '501 Patent, '502 Patent, and '648 Patent are related, there is a substantial overlap of the patents and applicable pages of each technical reference mentioned in the prosecution histories and the copies are provided together in Appendix B.

2. Foreign Counterparts to the '648 Patent

59. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the '648 Patent. **Exhibit 12.** No other foreign patents or patent applications corresponding to the '648 Patent are known to Masimo Corporation.

3. Non-Technical Description of the '648 Patent

60. Like the '501 and '502 Patents, the '648 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The '648 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The '648 Patent also includes limitations to novel arrangements of light sources and photodetectors. The '648 Patent also contains limitations to processors, network devices, and user interfaces, allowing the device to be easily used by consumers.

61. In sum, the invention of the '648 Patent provides a novel combination of features allowing for the measurement of a user's physiological parameters. [REDACTED]

[REDACTED].

62. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '648 Patent.

D. U.S. Patent No. 10,687,745

1. Identification of the Patent and Ownership by Masimo Corporation

63. Masimo Corporation owns by assignment the entire right, title, and interest in the '745 Patent, entitled "Physiological Monitoring Devices, Systems, and Methods," which issued on

June 23, 2020. (See **Exhibit 4**). The '745 Patent issued from U.S. Patent Application Serial No. 16/835,772, filed on March 31, 2020. The '745 Patent is a continuation of U.S. Patent Application No. 16/791,963, filed February 14, 2020, which is a continuation of U.S. Patent Application No. 16/532,065 filed August 5, 2019, which is a continuation of U.S. Patent Application No. 16/226,249 filed December 19, 2018, which is a continuation of U.S. Patent Application No. 15/195,199 filed June 28, 2016, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 62/188,430, filed July 2, 2015. A certificate of correction issued on the '745 Patent on September 22, 2020. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the '745 Patent is June 28, 2029.

64. The inventor of the '745 Patent, Ammar Al-Ali, assigned to Masimo Corporation the entire right, title, and interest in U.S. Patent Application No. 15/195199, and all divisions and continuations thereof, which includes the '745 Patent. **Exhibit 9**. Cercacor is the licensee of certain exclusive rights to the '745 Patent. **Confidential Exhibit 11**. The '745 Patent is valid, enforceable, and is currently in full force and effect.

65. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the certified prosecution history of the '745 Patent; and 2) an electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices E and F, respectively.

2. Foreign Counterparts to the '745 Patent

66. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn corresponding to the '745 Patent.

See **Exhibit 12**. No other foreign patents or patent applications corresponding to the '745 Patent are known to Masimo Corporation.

3. Non-Technical Description of the '745 Patent

67. The '745 Patent involves devices for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The devices include multiple optical sources that emit light at different wavelengths and numerous light detectors. The devices also include optical transmission materials configured to change the shape of the emitted light or diffusers to spread the light. The devices also contain light blocks to inhibit light from the optical sources from reaching the detectors before being attenuated by the user's skin. The light detectors are configured to detect the optical radiation from the tissue and output a respective signal stream responsive to this detection. This data is then processed by a processing device which outputs a measurement of the physiological parameter. The '745 Patent includes limitations to novel architecture features to implement the required measurement while limiting any light noise that could impact the accuracy of measurements. The '745 Patent also includes limitations to novel arrangements of light sources and photodetectors.

68. In sum, the invention of the '745 Patent provides a novel combination of features allowing for the measurement of a user's physiological parameters. [REDACTED]

69. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '745 Patent.

E. U.S. Patent No. 7,761,127

1. Identification of the Patent and Ownership by Cercacor

70. Cercacor owns by assignment the entire right, title, and interest in the '127 Patent, entitled "Multiple Wavelength Sensor Substrate," which issued on July 20, 2010. **Exhibit 5.** The '127 Patent issued from U.S. Patent Application Serial No. 11/366,209, filed on March 1, 2006. The '127 Patent claims priority to Provisional Application No. 60/657,596, filed on March 1, 2005, Provisional Application No. 60/657,281, filed on March 1, 2005, Provisional Application No. 60/657,268, filed on March 1, 2005, and Provisional Application No. 60/657,759, filed on March 1, 2005. Certificates of correction issued on the '127 Patent on January 4, 2011 and February 1, 2011. Pursuant to Commission Rule 210.12(a)(9)(xi) the expiration date of the '127 Patent is April 28, 2029.

71. The inventors of the '127 Patent, Ammar Al-Ali, Mohamed Diab, Marcelo Lamego, James Coffin, and Yassir Abdul-Hafiz, assigned to Masimo Laboratories, Inc. the entire right, title, and interest in U.S. Patent Application No. 11/366,209, and all patents granted thereof, which includes the '127 Patent. **Exhibit 10.** On August 2, 2010, Masimo Laboratories, Inc. changed its name to Cercacor Laboratories, Inc. **Exhibit 10.** Masimo is a licensee of certain exclusive rights to the '127 Patent. **Confidential Exhibit 11.** The '127 Patent is valid, enforceable, and is currently in full force and effect.

72. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by: 1) an electronic copy of the certified prosecution history of the '127 Patent; and 2) an electronic copy of each patent and applicable pages of each technical reference mentioned in the prosecution history. These materials are included in Appendices G and H, respectively.

2. Foreign Counterparts to the '127 Patent

73. Pursuant to Commission Rule 210.12(a)(9)(v), Complainants submit the attached list of foreign patents, foreign patent applications (not already issued as a patent), and each foreign

patent application that has been denied, abandoned, or withdrawn corresponding to the '127 Patent.

Exhibit 12. No other foreign patents or patent applications corresponding to the '127 Patent are known to Masimo Corporation.

3. Non-Technical Description of the '127 Patent

74. The '127 Patent discloses and involves a physiological sensor for the non-invasive measurement of physiological parameters such as blood oxygen saturation and pulse rate. The sensor includes a thermal mass, a plurality of light emitting sources operating at a plurality of wavelengths thermally coupled to the thermal mass, a temperature sensor to determine the bulk temperature of the thermal mass, and a detector capable of detecting light emitted from the light emitting sources after attenuation by the user's skin. Based on the bulk temperature of the thermal mass, the sensor is able to compensate for shifts in the LED wavelengths due to temperature.

75. In sum, the '127 Patent provides a novel combination of features allowing for the measurement of a user's physiological parameters. Confidential samples of rainbow[®] sensors that embody the claims of the '127 Patent are available upon request.

76. The foregoing non-technical description of the patented technology is not intended to limit, define, or otherwise affect the scope of the claimed inventions, nor is the non-technical description in any way intended to construe or define any word, phrase, term, or limitation recited in any claim of the '127 Patent.

F. Licensees

77. Masimo has licensed certain exclusive rights to the Masimo Patents to Cercacor. **Confidential Exhibit 11.** Cercacor has licensed certain exclusive rights to the Cercacor Patent to Masimo. **Confidential Exhibit 11.** There are no other licensees to the Asserted Patents.

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENT

78. Respondent manufactures, markets, sells for importation, imports and/or sells after importation into the United States products that directly infringe the '501 Patent, the '502 Patent, the '648 Patent, the '745 Patent, and the '127 Patent, either literally or under the doctrine of equivalents. Apple also induces the infringement of claims 20-24 and 26-27 of the '745 Patent by recommending, encouraging, and/or suggesting that consumers use their Apple Watch Series 6 with the consumer's iPhone in an infringing manner. On information and belief, Apple has knowledge of the '745 Patent because it monitors Masimo's patent filings. Apple will also have knowledge of the '745 Patent before the issuance of any requested relief in this Investigation, from the filing of this lawsuit itself and service of this complaint.

79. Respondent's Apple Watch Series 6 are sold under the below model names and numbers.

<u>Model Name</u>	<u>Model Number</u>
Apple Watch Series 6 (GPS) 40 mm case	A2291
Apple Watch Series 6 (GPS) 44 mm case	A2292
Apple Watch Nike (GPS) 40 mm case	A2291
Apple Watch Nike (GPS) 44 mm case	A2292
Apple Watch Series 6 (GPS + Cellular) Aluminum 40 mm case	A2293
Apple Watch Series 6 (GPS + Cellular) Aluminum 44 mm case	A2294
Apple Watch Nike (GPS + Cellular) 40 mm case	A2293
Apple Watch Nike (GPS + Cellular) 44 mm case	A2294
Apple Watch Series 6 (GPS + Cellular) Stainless Steel 44 mm case	A2293
Apple Watch Series 6 (GPS + Cellular) Stainless Steel 44 mm case	A2294

<u>Model Name</u>	<u>Model Number</u>
Apple Watch Hermes (GPS + Cellular) 40 mm case	A2293
Apple Watch Hermes (GPS + Cellular) 44 mm case	A2294
Apple Watch Edition (GPS + Cellular) Titanium 40 mm case	A2293
Apple Watch Edition (GPS + Cellular) Titanium 44 mm case	A2294

80. Photographs of a representative Apple Watch Series 6 (specifically Model No. 2291) are attached to this Complaint as **Exhibit 13**. A copy of information regarding the Apple Watch Series 6 from Apple's website is attached hereto as **Exhibit 14**. Samples of the Apple Watch Series 6 can be made available upon request.

81. On information and belief, Respondent and others on its behalf manufacture the Accused Products at least in China, and then import them into the United States, sell them for importation into the United States, and/or sell them within the United States after importation.

82. These acts of Respondent constitute infringement of the Asserted Patents.

83. Claim charts demonstrating how a representative Apple Watch Series 6 infringes the '501 Patent, the '502 Patent, the '648 Patent, '745 Patent, and the '127 Patent are attached as **Confidential Exhibits 15, 16, 17, 18, and 19**, respectively. While a representative Apple Watch Series 6 is shown in the claim charts in **Confidential Exhibits 15, 16, 17, 18, and 19**, Respondent does not distinguish in any relevant manner between other model numbers of the Apple Watch Series 6 in their marketing or promotional materials, and Masimo alleges that all of Respondent's Apple Watch Series 6 identified in ¶79 above infringe at least one Asserted Claim of the Asserted Patents.

84. Masimo has not licensed or otherwise authorized Respondent to make, use, sell, offer to sell, or import the Accused Products.

85. Respondent has sought to capitalize on Masimo's extensive research and development efforts.

VII. THE DOMESTIC INDUSTRY RELATED TO ASSERTED PATENTS

86. A domestic industry exists or is in the process of being established as defined by 19 U.S.C. §§ 1337(a)(2)–(3) relating to Masimo's significant investment in plant and equipment; significant employment of labor or capital; research and development activities; and substantial investment in exploitation of the patents, including engineering with respect to Masimo's physiological measurement devices and monitors. With respect to the '501 Patent, the '502 Patent, the '648 Patent, and the '745 Patent, Masimo's activities in the United States with respect to [REDACTED]

[REDACTED]—constitute a domestic industry for purposes of Section 337. To the extent it is determined that a domestic industry [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] is protected by one or more claims of each of the '501 Patent, the '502 Patent, the '648 Patent, and the '745 Patent.

87. With respect to the '127 Patent, Masimo's activities in the United States with respect to at least its rainbow[®] sensor technology constitute a domestic industry for purposes of Section 337. Masimo's rainbow[®] sensors—including the, RD rainbow[®] Set-2, rainbow[®] R1, rainbow[®] R25, rainbow[®] R20, rainbow[®] DCI SC 200, rainbow[®] DCI SC 400, rainbow[®] DCI SC 1000, rainbow[®] DCI mini SC-200, rainbow[®] DCI mini SC-400, rainbow[®] DCI mini SC-1000,

rainbow[®] Super DCI mini SC-200, rainbow[®] Super DCI mini SC-400, rainbow[®] Super DCI mini-SC-1000, rainbow[®] DCI, rainbow[®] DCI-dc, RD rainbow[®] 8 λ SpCO Adhesive Sensor, LNCS-II[™] rainbow[®] DCI[®] 8λ SpHb, LNCS-II[™] rainbow[®] DCIP[®] 8λ SpHb, LNCS-II[™] rainbow[®] DCI[®] 8λ SpCO, and LNCS-II[™] rainbow[®] DCIP[®] 8λ SpCO—are protected by at least one claim of the '127 Patent.

A. Technical Prong

88. Masimo has designed and developed its domestic industry products through its extensive research and development efforts based almost entirely in the United States. Moreover, Masimo [REDACTED] in the United States and manufactures a material amount of the components of its rainbow[®] sensors in the United States. As set forth in more detail herein, Masimo's domestic industry products incorporate the inventions claimed in one or more claims of the Asserted Patents.

89. Drawings, photographs, or other visual representations of representative Masimo domestic industry products (specifically, [REDACTED] and certain rainbow[®] sensors) are attached hereto as **Confidential Exhibit 20 and Confidential Exhibit 21**. Claim charts showing how a representative Masimo domestic industry product practices exemplary claims of the '501 Patent, the '502 Patent, the '648 Patent, the '745 Patent, and the '127 Patent are attached hereto as **Confidential Exhibits 15, 16, 17, 18 and 19**, respectively. Additional information regarding the domestic industry products is found in the Declaration of Bilal Muhsin, attached hereto as **Confidential Exhibit 27**.

B. Economic Prong

90. The domestic industry in this case is based on significant investments Masimo has made and/or plans to make and activities Masimo has undertaken and/or plans to undertake in the

United States relating to products protected by one or more claims of the Asserted Patents. These investments and activities include research and development, manufacturing, testing, and engineering for the Masimo domestic industry products. Specific, non-limiting examples of Masimo's substantial investments and activities related to the Asserted Patents are set forth in the confidential declaration of Micah Young, attached to this complaint as **Confidential Exhibit 28**.

91. Masimo employs a significant number of employees in its U.S facilities in Irvine, California. These employees devote substantial personnel-hours toward the research and development, testing and engineering for the Masimo domestic industry products. The confidential declaration of Micah Young sets forth details regarding the investments it has made in these U.S. employees.

92. Masimo also invests capital toward manufacturing and research and development for products protected by the Asserted Patents. The confidential declaration of Micah Young provides additional details regarding Masimo's capital investments.

93. In addition, Masimo has made substantial investments in plant and equipment in the United States. Masimo's facilities in Irvine, California, houses activities for research and development, manufacturing, testing and engineering for the Masimo domestic industry products. Masimo also owns a facility in New Hampshire where manufacturing activities for its rainbow[®] sensors take place. The confidential declaration of Micah Young includes further non-limiting examples of Masimo's investments in this category.

94. To the extent it is determined that a domestic industry does not currently exist, Masimo is in the process of establishing a domestic industry with respect to the Masimo Patents because it is actively engaged in the steps leading to the exploitation of its intellectual property rights, and there is a significant likelihood that an industry will be established in the United States

in the future [REDACTED]

[REDACTED]

[REDACTED]. Further, non limiting examples regarding the active

steps taken by Masimo to establish a domestic industry are included in the confidential declaration of Micah Young filed herewith as **Confidential Exhibit 28**.

VIII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

95. Respondent, and/or others on its behalf, manufactures the Accused Products at least in China, and then imports them into the United States, sells them for importation into the United States, and/or sells them after importation into the United States. Respondent sells and offers for sale the Accused Products directly to customers in the United States. Respondent stated in a press release dated September 15, 2020, that it was introducing the Series 6 in the United States for sale starting on September 18, 2020. **Exhibit 29**

96. Prior to filing this Complaint, a representative Apple Watch Series 6 product was purchased on April 19, 2021, in the United States. A copy of the invoice of this purchase is attached hereto as **Confidential Exhibit 30**. The packaging of this Accused Product indicates that it was made outside the United States. Photographs of the product packaging for this Apple Watch product, showing that it was made in China, are attached hereto as **Exhibit 31**.

97. In addition, Apple's 10K filed with the SEC on January 28, 2021 states that "[s]ubstantially all of the Company's hardware products are manufactured by outsourcing partners that are located primarily in Asia, with some Mac computers manufactured in the U.S. and Ireland." **Exhibit 32**.

IX. CLASSIFICATION OF THE INFRINGING PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

98. Upon information and belief, the Accused Products may be classified under at least the following heading of the Harmonized Tariff Schedules of the United States: 8517.62.0090. This HTS identification is illustrative and not exhaustive. The identification is not intended to limit the scope of the Investigation, nor is it intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

X. RELATED LITIGATION

99. On January 9, 2020, Masimo Corp. and Cercacor filed suit in the United States District Court for the Central District of California, Case No. 8:20-cv-00048. In that case, Complainants assert that Respondent Apple has, *inter alia*, engaged in trade secret misappropriation and has infringed patents not asserted in this complaint by the sale of the certain products, including the Apple Watch Series 6. Complainants also seek a declaration of ownership of several patents and applications filed by Apple. That case is currently pending before the district court, but Complainants' patent infringement claims are stayed pending resolution of the below referenced *inter partes* review proceedings.

100. Respondent has filed numerous petitions for *inter partes* review of the patents involved in Case No. 8:20-cv-0048, none of which are asserted in this complaint: IPR2020-01520 (Instituted March 2, 2021); IPR2021-00208 (Instituted June 3, 2021); IPR2020-01521 (Instituted April 14, 2021); IPR2021-00193 (Instituted June 3, 2021); IPR2021-00195 (Instituted June 3, 2021); IPR2021-00209 (Instituted June 3, 2021); IPR2020-01524 (Instituted April 16, 2021); IPR2020-01722 (Instituted May 12, 2021); IPR2020-01723 (Institution denied May 12, 2021); IPR2020-01536 (Instituted March 2, 2021); IPR2020-01537 (Instituted March 2, 2021); IPR2020-

01538 (Instituted March 2, 2021); IPR2020-01539 (Instituted March 2, 2021); IPR2020-01526 (Instituted April 16, 2021); and IPR2020-01523 (Instituted April 14, 2021).

101. There have been no other foreign or domestic court or agency litigations involving any of the Asserted Patents.

XI. REQUESTED RELIEF

102. WHEREFORE, by reason of the foregoing, Complainants request that the United States International Trade Commission:

- a) institute an immediate investigation pursuant to 19 U.S.C. § 1337 into the violations of that section based on Respondent's unlawful importation into the United States, sale for importation into the United States, and/or sale in the United States after importation of certain light-based physiological measurement devices and components thereof that infringe one or more claims of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and/or 7,761,127;
- b) schedule and conduct a hearing pursuant to Section 337(c), for the purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337;
- c) determine that there has been a violation of Section 337 by Respondent;
- d) issue a permanent exclusion order, pursuant to 19 U.S.C. § 1337(d), excluding from entry into the United States all of Respondent's light-based physiological measurement devices and components thereof, including Apple Watch Series 6, that infringe one or more claims of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and/or 7,761,127;

- e) issue a permanent cease and desist order, pursuant to 19 U.S.C. § 1337(f), directing Respondent to cease and desist from importing, marketing, advertising, demonstrating, warehousing of inventory for distribution, sale, or use of certain light-based physiological measurement devices and components thereof that infringe one or more claims of U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and/or 7,761,127;
- f) impose a bond upon Respondent should Respondent continue to import infringing articles during the 60-day Presidential Review period pursuant to 19 U.S.C. § 1337(j); and
- g) grant such other and further relief as the Commission deems appropriate and just under the law, based on the facts complained of herein and determined by the investigation.

Respectfully submitted,

Dated: July 7, 2021

By: /s/ Jonathan E. Bachand
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VERIFICATION OF FIRST AMENDED COMPLAINT

I, Jonathan E. Bachand, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), under penalty of perjury, that the following statements are true:

1. I am Counsel for Complainants Masimo Corporation and Cercacor Laboratories, Inc. and I am duly authorized to sign the First Amended Complaint on behalf of Complainants;
2. I have read the foregoing First Amended Complaint;
3. To the best of my knowledge, information, and belief, based upon reasonable inquiry, the foregoing First Amended Complaint is well-founded in fact and is warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law, or the establishment of new law;
4. The allegations and other factual contentions have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and
5. The foregoing First Amended Complaint is not being filed for an improper purpose, such as to harass or cause unnecessary delay or needless increase in the cost of litigation.

Executed this 7th day of July, 2021.

/s/ Jonathan E. Bachand
Jonathan E. Bachand
Counsel for Complainants
Masimo Corporation and Cercacor
Laboratories, Inc.

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Charles E. Bullock
Chief Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**RESPONSE OF APPLE INC. TO FIRST AMENDED COMPLAINT AND NOTICE OF
INVESTIGATION**

RESPONDENT

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30. Apple lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30, and therefore denies them.

31. Apple admits the Asserted Patents purport to claim certain devices and/or components used in the non-invasive measurement of physiological parameters. Apple denies that the Asserted Patents cover anything “novel” or any improvements. Apple denies the characterizations of the Asserted Patents to the extent inconsistent with the language of the specifications and claims. The remaining statements and allegations of Paragraph 31 contain opinions and legal arguments rather than factual assertions and therefore require no response is required; to the extent a response is required, Apple denies them.

32. Apple admits that in 2013, representatives of Apple and Masimo held a meeting and that Apple and Masimo entered into certain mutual confidentiality agreements [REDACTED]

[REDACTED] Apple denies the remaining allegations in Paragraph 32.

33. Apple admits that it employed Michael O’Reilly beginning in July 2013 as its Vice President of Medical Technology. Apple admits that Mr. O’Reilly has assisted with projects related to wellness and non-invasive measurement of physiological parameters. Apple admits that Mr. O’Reilly met with the FDA on behalf of Apple in or around December 2013 regarding the FDA’s regulation of consumer products. Apple lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33, and therefore denies them.

34. Apple admits that it hired Marcelo Lamego in 2014. Apple admits that Mr. Lamego is named as an inventor on four of the Asserted Patents. Apple denies that it “systematically recruited other key Masimo personnel, such as Marcelo Lamego.” Apple lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 34, and therefore denies them.

35. Apple lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35, and therefore denies them.

36. Apple admits that it received a letter from outside counsel for Cercacor Laboratories, Inc. on or around January 24, 2014. Apple denies that the letter contains the language quoted in the third sentence of Paragraph 36 of the Complaint. Apple admits that the letter contains the language quoted in the fourth sentence of Paragraph 36 of the Complaint. Apple lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 36, and therefore denies them.

37. Apple denies the allegations in Paragraph 37.

38. Apple admits that it announced the first version of the Apple Watch in September 2014 and began shipping that product in April 2015. Apple admits that the Apple Watch Series 6 is the first Apple Watch incorporating a Blood Oxygen feature. Apple denies the remaining allegations in Paragraph 38.

39. Apple admits that the Apple Watch Series 6 is an electronic smartwatch that incorporates a Blood Oxygen feature. Apple admits that claim charts purporting to compare one or more of the asserted claims to the Apple Watch Series 6 are attached as Exhibits 15-19 to the Complaint. Apple denies the remaining allegations contained in Paragraph 39.

40. Apple admits that the Apple Watch Series 6 is imported into and sold within the United States by or on behalf of Apple. Apple admits that it maintains inventory of the Apple Watch Series 6 in the United States. Apple denies any remaining allegations contained in Paragraph 40.

41. The statements and allegations of Paragraph 41 contain opinions and legal arguments rather than factual assertions and therefore require no response; to the extent a response is required, Apple denies them.

V. THE ASSERTED PATENTS

- **U.S. Patent No. 10,912,501**

42. Apple admits that the '501 patent is entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," and that it issued on February 9, 2021. Apple further admits that the '501 patent issued from U.S. Patent Application Serial No. 17/031,356, filed on September 24, 2020. Apple admits that the face of the '501 patent states that the '501 patent is purportedly a continuation of U.S. Patent Application No. 16/834,538, filed March 30, 2020, which is a continuation of U.S. Patent Application No. 16/725,292, filed December 23, 2019, which is a continuation of U.S. Patent Application No. 16/534,949, filed August 7, 2019, which is a continuation of U.S. Patent Application No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. Patent Application No. 16/261,326, filed January 29, 2019, which is a continuation of U.S. Patent Application No. 16/212,537, filed December 6, 2018, which is a division of U.S. Patent Application No. 14/981,290 filed December 28, 2015, which is a continuation of U.S. Patent Application No. 12/829,352 filed July 1, 2010, which is a continuation of U.S. Patent Application No. 12/534,827 filed August 3, 2009 (now abandoned). Apple admits that the face of the '501 patent states that U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,528 filed July 2, 2009, which is a continuation-in-part of U.S. Design Patent Application Nos. 29/323,408 and 29/323,409, both filed August 25, 2008. Apple admits that the face of the '501 patent states that U.S. Patent Application No. 12/829,352 is also a continuation-in-part of U.S. Patent Application No. 12/497,523 filed July

76. The allegations of Paragraph 76 contain opinions and legal arguments rather than factual assertions and therefore require no response; to the extent a response is required, Apple denies them.

- **Licensees**

77. Apple lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 77, and therefore denies them.

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENT

78. Apple admits that it has knowledge of the '745 patent from the filing and service of this Complaint. Apple denies the remaining allegations contained in Paragraph 78.

79. Apple admits that Apple Watch Series 6 products are sold in the United States under the model names and numbers listed in Paragraph 79 of the Complaint, with the exception that the Apple Watch Series 6 (GPS + Cellular) Stainless Steel 44 mm case is sold only under the model number A2294, not model number A2293. The Apple Watch Series 6 (GPS + Cellular) Stainless Steel 40 mm case is sold under the model number A2293. Apple denies any remaining allegations contained in Paragraph 79.

80. Apple admits that Exhibit 13 purports to be photographs of an Apple Watch Series 6 with the model number A2291 and the packaging thereto. Apple further admits that Exhibit 14 purports to be information regarding the Apple Watch Series 6 from Apple's website. Apple denies any remaining allegations contained in Paragraph 80.

81. Apple admits that at least some manufacturers of the Apple Watch Series 6 are located in China. Apple admits the Apple Watch Series 6 is sold for importation into the United States, imported into the United States, and/or sold after importation into the United States by or on behalf of Apple. Apple denies any remaining allegations in Paragraph 81.

82. Apple denies the allegations in Paragraph 82.

83. Apple admits that claim charts purporting to compare one or more of the asserted claims to the Apple Watch Series 6 are attached as Confidential Exhibits 15-19 to the Complaint. Apple denies that the Apple Watch Series 6 or any Apple product infringes any valid and enforceable claims of the Asserted Patents. Apple denies any remaining allegations in Paragraph 83.

84. Apple lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 84, and therefore denies them.

85. Apple denies the allegations in Paragraph 85.

VII. THE DOMESTIC INDUSTRY RELATED TO ASSERTED PATENTS

86. Apple lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86, and therefore denies them.

87. Apple lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 87, and therefore denies them.

- **Technical Prong**

88. Apple lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 88, and therefore denies them.

89. Apple admits that Confidential Exhibits 20 and 21 purport to be visual representations of Masimo's products. Apple admits that claim charts purporting to compare one or more of the asserted claims to Masimo's products are attached as Confidential Exhibits 22-26 to the Complaint. Apple admits that Confidential Exhibit 27 purports to be a declaration made by an individual named Bilal Muhsin. Apple lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 89, and therefore denies them.

- **Economic Prong**

90. Apple admits that Confidential Exhibit 28 purports to be a declaration made by an individual named Micah Young. Apple lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 90, and therefore denies them.

91. Apple admits that Confidential Exhibit 28 purports to be a declaration made by an individual named Micah Young. Apple lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 91, and therefore denies them.

92. Apple admits that Confidential Exhibit 28 purports to be a declaration made by an individual named Micah Young. Apple lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 92, and therefore denies them.

93. Apple admits that Confidential Exhibit 28 purports to be a declaration made by an individual named Micah Young. Apple lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 93, and therefore denies them.

94. Apple admits that Confidential Exhibit 28 purports to be a declaration made by an individual named Micah Young. Apple lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 94, and therefore denies them.

VIII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

95. Apple admits that at least some manufacturers of the Apple Watch Series 6 are located in China. Apple admits the Apple Watch Series 6 is sold for importation into the United States, imported into the United States, and/or sold after importation into the United States by or on behalf of Apple. Apple admits that it sells and offers for sale the Apple Watch Series 6 directly to customers in the United States. Apple admits that it stated in a press release dated September

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**


Inv. No. 337-TA-1276

ORDER NO. 4: ISSUING REPLACEMENT GROUND RULES

(September 22, 2021)

On September 13, 2021, the instant case was reassigned from the Chief Administrative Law Judge to the undersigned. Effective immediately, the attached Ground Rules shall replace the original Ground Rules and shall control the remainder of this investigation.

SO ORDERED.


Monica Bhattacharyya
Administrative Law Judge

- (d) A proposed agenda for the pre-hearing conference.
- (e) Estimated date and approximate length for appearance of each witness. The parties shall confer on estimated dates and approximate length prior to submission of their pre-hearing statements.
- (f) Certification regarding good faith efforts to settle.

9.2 Pre-hearing Brief

On or before the date set forth in the procedural schedule, each party shall file a pre-hearing brief not exceeding 250 pages. To the extent there is more than one complainant and/or respondent in an investigation, complainants and/or respondents shall coordinate their efforts and submit a single brief. Exceptions to this rule will be made on a case-by-case basis.

The pre-hearing brief shall be prefaced with a table of contents and a table of authorities. The pre-hearing brief shall set forth a party's contentions on each of the proposed issues, including specific citations to legal authorities and record evidence, and shall conform to the general outline set forth in Appendix B hereto. With respect to the issues of infringement, validity, and the technical prong of domestic industry, the parties should present their briefing on a limitation-by-limitation basis. The parties shall meet and confer prior to filing the pre-hearing briefs in order to agree on an outline, so that each of the submitted briefs addresses the issues in the same order. If any party has issues that are not specifically named in this general outline, the parties may insert these issues where appropriate.

Any contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-hearing brief.

9.3 High Priority Objections

High priority objections may address proposed exhibits or testimony. The parties must confer before filing objections, and the statement of high priority objections shall include a certification pursuant to Ground Rule 3.2. No party shall place more than ten objections on the high priority list. The parties should not attempt to circumvent this limitation by including numerous subsections in their objections.

High priority objections and responses thereto shall include the exhibit(s) that is the subject of the objection and/or exhibit(s) that is referenced or discussed in the objection or response. Any high priority objection that does not include said exhibit(s) will not be considered.

Native files (such as Excel, videos) may be included with the electronic copy of exhibits submitted to the Administrative Law Judge.

12.4 Commission's Copy

The Commission set of exhibits shall be submitted in electronic format. The format for these exhibits is set forth at:

http://www.usitc.gov/docket_services/documents/EDIS3UserGuide-CDSsubmission.pdf.

There are twenty-four standard exhibit categories: CX, CDX, CPX, RX, RDX, RPX, JX, JDX, JPX, SX, SDX, SPX, CX-[four-digit number]C, CDX-[four-digit number]C, CPX-[four-digit number]C, RX-[four-digit number]C, RDX-[four-digit number]C, RPX-[four-digit number]C, JX-[four-digit number]C, JDX-[four-digit number]C, JPX-[four-digit number]C, SX-[four-digit number]C, SDX-[four-digit number]C, and SPX-[four-digit number]C.

The Commission set of exhibits shall be uploaded using the Box platform with separate folders for each type of exhibit, *e.g.*, CX (Public), CX (Confidential), etc. The exhibits must be PDF files and any file larger than 25MB shall be broken up into separate files. A Table of Contents file in PDF format which lists the names of all files in each folder should be created and included in each folder. Rejected exhibits should be provided in separate folders.

Any exhibits that are not included with the Commission exhibits and on the final exhibit list at the conclusion of the hearing will not be considered as part of the record to be certified to the Commission when the final initial determination issues.

12.4.1 Native Files

Native files (such as Excel, videos) should be printed to PDF and placed in the appropriate folder. If the native file cannot be printed to PDF in a legible manner, a placeholder should be placed in the appropriate folder indicating that the exhibit is a native file. In addition to the PDF files, parties may submit the native files in separate folders that are explicitly identified, *e.g.*, CX (Native).

12.5 Exhibit Set for the Office of General Counsel

No later than seven (7) days after the submission of post-hearing reply briefs, the parties shall contact the Office of General Counsel regarding submission of exhibits to that office.

13. Post-hearing Briefs

13.1 Initial Post-hearing Briefs; Filing and Content

On or before the date set forth in the procedural schedule, each party shall file a post-hearing brief (and submit the courtesy copy required by Ground Rule 1.3). The post-hearing

brief shall discuss the issues and evidence tried within the framework of the general issues determined by the Commission's Notice of Investigation and those issues that are included in the pre-hearing brief and any permitted amendments thereto. All other issues shall be deemed waived.

The parties are expected to follow the outline used in pre-hearing briefs in the post-hearing brief, except that the parties should remove references to any issue that the parties agree is no longer in dispute.

A reasonable page limit will be imposed for all post-hearing briefs, which will be determined on a case-by-case basis. Parties are required to use double-spacing (with the exception of headings, footnotes, quotations, etc.), at least 12-point font, and one-inch margins (excluding headers for CBI and footers, such as page numbers). If the parties have any questions regarding the acceptable formatting requirements for post-hearing briefs, they should contact the Administrative Law Judge's attorney-advisor.

To the extent there is more than one complainant and/or respondent in an investigation, complainants and/or respondents shall coordinate their efforts and submit a single brief. Exceptions to this rule will be made on a case-by-case basis. This rule shall also apply to post-hearing reply briefs.

13.2 Post-hearing Reply Briefs; Filing and Content

On or before the date set forth in the procedural schedule, each party shall file a post-hearing reply brief. The post-hearing reply brief shall discuss the issues and evidence discussed in the initial post-hearing briefs of each opposing party.

A reasonable page limit will be imposed on all post-hearing reply briefs, which will be determined on a case-by-case basis. The rules relating to post-hearing briefs detailed in Ground Rule 13.1 also apply to reply briefs.

13.3 Citations to Evidence

When citing to witness testimony, the party must include a parenthetical identifying the witness whose testimony is being cited. For example, if a party is citing to the trial testimony of their witness, Dr. Smith, the party should include the citation: Tr. (Smith) at 123:1-124:14. If citing to the direct testimony of Dr. Smith, the party should include the citation: CX-0001C (Smith) at Q/A 1-5. This rule also applies if the cited exhibit is testimony received during a deposition.

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

**ORDER NO. 5: INITIAL DETERMINATION EXTENDING TARGET DATE BY
ONE MONTH; RESCHEDULING HEARING DATES; ORDERING
SUBMISSION OF REVISED PROPOSED PROCEDURAL
SCHEDULE**

(September 22, 2021)

On September 13, 2021, the investigation was assigned to the undersigned. Replacement Ground Rules for the investigation have been set forth in Order No. 4, issued concurrently herewith. The target date in this investigation was previously set to be Friday, December 16, 2022, and an evidentiary hearing was set for the week of May 23-27, 2022, with a *Markman* hearing on Thursday, February 3, 2022. Order No. 3 (Sept. 1, 2021). The parties submitted a proposed procedural schedule on September 17, 2021, based on the target date and hearing dates set forth in Order No. 3.

The undersigned has determined to extend the target date and to reschedule the hearing dates in this investigation based on a review of the parties' proposed procedural schedule, in consideration of the procedures set forth in the current Ground Rules, and in view of the undersigned's responsibilities in other investigations.¹

¹ The undersigned currently has an initial determination due on July 28, 2022 in Inv. No. 337-TA-1267 and an initial determination due on August 5, 2022 in Inv. No. 337-TA-1273. Under the 16-month target date, the initial determination in this investigation would issue no later than August 16, 2022.

11.8.2 Corrections to Transcripts

If a transcript needs to be corrected after the conclusion of the hearing, the party requesting the change shall do so through a motion. Once an order issues adopting the proposed correction, it is incumbent upon the party requesting the change to send a copy of the order to the court reporting service so that the corrections can be made.

12. Submission of Final Exhibit Lists and Final Exhibits

On the same day that initial post-hearing briefs are due, the parties shall each submit the following: [1] the final exhibit lists; and [2] an electronic version of the final set of exhibits to the Administrative Law Judge for use in drafting the final initial determination.⁹

On the date that reply post-hearing briefs are due, the parties shall submit a Commission set of exhibits, with rejected exhibits submitted under separate cover and so marked.

Each side is only responsible for submitting its own exhibits.¹⁰ Source code (both paper and electronic copies) should be submitted in a manner jointly agreed upon by the parties.

12.1 Final Exhibit List

Each party must submit a final exhibit list prepared in accordance with Ground Rule 9.5.1 reflecting the status of all exhibits, including those admitted or rejected during the hearing. Withdrawn exhibits do not need to be on the exhibit list.

The parties should submit three versions of the final exhibit list: (1) a list identifying all confidential exhibits; (2) a list identifying all public exhibits; and (3) a master list with all exhibits (both confidential and public). Each side is only responsible for submitting its own exhibit list, except that Complainant(s) is also responsible for submitting the three versions of the joint exhibit lists.

Each party should also submit a list of rejected exhibits. Only one version of this list is required.

12.2 Administrative Law Judge's Electronic Copy

The parties should provide an electronic copy of the exhibits. This electronic copy shall be uploaded using the Box platform and need not be separated or broken up in the manner described below for the Commission's set of exhibits.

⁹ Demonstrative exhibits should be included.

¹⁰ Complainant(s) are responsible for submitting joint exhibits.

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before the Honorable Monica Bhattacharyya
Administrative Law Judge

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S MOTION FOR SANCTIONS

Pursuant to Commission Rule 210.4, Respondent Apple Inc. moves for sanctions against Complainants Masimo Inc. and Cercacor Technologies Inc. for making materially false statements in their First Amended Complaint and supporting declarations concerning the existence of a so-called [REDACTED] and then engaging in discovery misconduct to obstruct the truth. The Complaint describes the [REDACTED] at considerable length—in the present tense—including through a sworn declaration by Masimo's Chief Operating Officer Bilal Muhsin and attached images. These statements were made in an apparent effort to demonstrate the present existence, present features, and present functionality of the purported device—the protection of which is the very predicate for this Investigation as to four asserted patents. The Complaint also states that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Despite constant and ongoing obstruction by the Complainants, discovery has revealed the following:

- [REDACTED] was not complete on the

[REDACTED]

[REDACTED]

date the Complaint was filed—and may not even be complete today, many months later.

- In the months since the case began, Complainants have not identified [REDACTED]
[REDACTED]
[REDACTED] Over and over, Apple has made the “request” for [REDACTED]
[REDACTED] and over and over, Complainants have refused to meet that request.
- Complainants cannot confirm that they [REDACTED]
[REDACTED].
- As of service of this motion, on December 17, 2021 (when Respondent served Complainants to provide the seven days of review prescribed by Rule 210.4), Complainants have not [REDACTED]
- On December 15, Masimo’s Chief Operating Officer, Bilal Muhsin, testified that [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

These and other facts demonstrate that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The nascent and incomplete [REDACTED] is not the type of “domestic industry” that this agency is designed to protect. But even setting aside that legal problem, as a factual matter [REDACTED] is flatly inconsistent with the factual allegations in the Complaint and supporting declarations. And rather than acknowledge the truth, Complainants have engaged in months of discovery malfeasance, including by providing discovery responses that attempted to create a cloud of misinformation and obscure the truth.

Again and again, Complainants have refused to answer the simplest question: if there was [REDACTED] that matched the descriptions in the Complaint and supporting declarations—and existed at the time of the complaint—[REDACTED] When asked during a discovery teleconference with the Administrative Law Judge in November if Complainants could identify such a device, Complainants’ counsel said [REDACTED]. When Apple’s counsel has asked this question, over and over, Complainants have responded [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

It is now clear that this case never should have been brought for four of the five asserted patents. Complainants chose to file a complaint and declarations that contain false and misleading statements, and then tried repeatedly to obstruct Apple’s investigation into the truth. Because

Complainants' misstatements go to the very basis for the Commission's jurisdiction in this Investigation, Apple respectfully requests that the ALJ sanction Complainants, including by terminating the Investigation and awarding Apple its attorneys' fees.

Statement of Compliance With Commission Rule 210.4(d)(1)(i) and Ground Rule 3.2

As required by Commission Rule 210.4(d)(1)(i), Respondent Apple Inc. served a copy of this motion on counsel for Complainants Masimo Inc. and Cercacor Laboratories, Inc. on December 17, 2021 and requested they withdraw their Complaint within seven days. Complainants informed Apple on December 24 that they would not withdraw the Complaint.

Further, pursuant to Ground Rule 3.2, Apple certifies that it made reasonable, good-faith efforts to resolve this matter with Complainants at least two days prior to filing this motion.

DATED: December 28, 2021

Respectfully submitted,

/s/ Sarah R. Frazier

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Counsel for Respondent Apple Inc.

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**MEMORANDUM IN SUPPORT OF
RESPONDENT APPLE INC.'S MOTION FOR SANCTIONS**

Complainants Masimo Inc. and Cercacor Laboratories, Inc. assert in their First Amended Complaint that “Masimo’s activities in the United States with respect to at least its [REDACTED] constitute a domestic industry for purposes of Section 337.” Complainants submitted images of [REDACTED] claim charts purporting to describe [REDACTED]

[REDACTED] and a declaration from Masimo’s Chief Operating Officer Bilal Muhsin containing [REDACTED] And,

Complainants repeatedly represented that [REDACTED]
[REDACTED]
[REDACTED]

Yet, more than four months into this Investigation, and after dozens of discovery requests, two “inspections,” and four teleconferences with the ALJ, Complainants have failed to identify or produce [REDACTED]

[REDACTED]

the representation or disputed portion thereof was objectively reasonable under the circumstances.”

Id. In applying Rule 210.4, the Commission has found a complainant’s failure to undertake a reasonable pre-suit investigation to be not “objectively reasonable.” *See, e.g., Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 63 at 29-31, 34 (Feb. 6, 2007) (sanctioning complainants because their pre-filing inquiry was inadequate and finding complainants “actively misrepresented facts” to support their domestic industry economic prong allegations); *see also Certain Concealed Cabinet Hinges*, Inv. No. 337-TA-289, Comm’n Opinion (Jan. 8, 1990) (dismissing complaint where complainants’ domestic industry allegations were misleading).

Where parties have been found to violate Rule 210.4, such as by including allegations in the Complaint that were later shown to be false, the Commission has imposed monetary and other sanctions. 19 C.F.R. § 210.4(d)(2) (“the sanction may consist of, or include, directives of a nonmonetary nature, and order to pay a penalty, or ... directing payment to the movant of some or all of the reasonable attorney’s fees and other expenses incurred as a direct result of the violation”); *see also Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, Recommended Determination at 1-2 (May 14, 1997) (ordering complainants to pay double the respondents’ attorneys’ fees for filing their complaint for an improper purpose); *Point of Sale Terminals, supra*, at 34 (sanctioning Complainants \$30,000); *Certain Concealed Cabinet Hinges, supra*, at 7 (dismissing complaint and terminating the investigation with prejudice).

III. ARGUMENT

From the outset, Apple has sought discovery concerning the existence, features, and functionality of [REDACTED]

[REDACTED]. Apple’s efforts began with the most basic requests: to produce [REDACTED] More than four months into

[REDACTED]

discovery, however, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Complainants have tried to hide this basic fact with a blizzard of misleading discovery tactics, even going so far as to [REDACTED]

[REDACTED] See DocID 758291 [12/2/21 Complainants' Written Explanation of Dispute] at 1-2; *see also* Ex. T at 5:18-20 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Indeed, Complainants' corporate witness on topics concerning the veracity of the allegations in the Complaint, Bilal Muhsin (who also submitted a declaration supporting the allegations in the Complaint), [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See Section I.B.2.d, *supra*.

Recently, Complainants have tried to pivot and [REDACTED]

[REDACTED]

[REDACTED]

Doc ID 756914 [11/18/21

[REDACTED]

Complainants' Written Explanation of Dispute]. Of course, the false narrative is not of Apple's creation but originated with the Complaint itself. [REDACTED]

[REDACTED]

[REDACTED] and in light of Complainants' misconduct during discovery, there can simply be no dispute that Complainants' representations in the Complaint were materially false and violated Commission Rule 210.4. Accordingly, sanctions, including termination of this Investigation and payment of Apple's attorneys' fees and costs, are warranted.

A. The Complaint Represented That [REDACTED]

The Complaint unmistakably relies on [REDACTED] to support its claim of domestic industry for four of the five asserted patents. The text of the Complaint itself represents that [REDACTED]

[REDACTED] constitute a domestic industry for purposes of Section 337" and that [REDACTED]

[REDACTED] Compl. ¶ 86. The Complaint likewise represents that [REDACTED]

[REDACTED] *Id.* ¶¶ 47, 54, 61, 68.

The Complaint includes claim charts and a sworn declaration from Masimo's Chief Operating Officer, Bilal Muhsin, [REDACTED]

A series of horizontal black bars of varying lengths, representing redacted text. The bars are stacked vertically, with some being longer than others, creating a jagged, irregular pattern. The bars are solid black and have no text or other markings on them.

B. Complainants' Discovery Responses And Misconduct Compel The Conclusion That No [REDACTED] Actually Existed At The Time Of The Complaint.

The record in this Investigation leaves no doubt that Complainants did not possess [REDACTED] [REDACTED] relied upon in the Complaint, and that Complainants misled the Commission about what it did have. [REDACTED]

[REDACTED] to support their domestic industry claim, to comply with the ALJ's orders, and to avoid sanction. Yet despite dozens of opportunities to [REDACTED] available to Apple, Complainants have failed to do so, choosing instead to obstruct Apple's efforts to uncover the truth.

1. Complainants Have Failed To Identify [REDACTED] That Matches The Descriptions In The Complaint And Was In Existence At The Time Of The Complaint.

As detailed above, Apple has propounded a series of straightforward requests to Complainants seeking identification of [REDACTED] identified in the Complaint. Among the most fundamental requests was Apple's Request for Production No. 124, which sought [REDACTED]

[REDACTED] Ex. A at 110-111 (response to Interrogatory No. 124, Ex. B at 3; *see also* Ex. D at 4

EXHIBIT N

From: Frazier, Sarah
Sent: Wednesday, November 24, 2021 1:56 PM
To: Kendall.Loebbaka
Cc: Masimo.AppleITC; WH Apple-Masimo 1276 Service List
Subject: RE: ITC No 337-TA-1276 (CBI)

[REDACTED]

Kendall,

This is not a good faith identification of [REDACTED], and only continues the litigation misconduct that we have raised many times, including in Joe Mueller's letter yesterday. We will not let your misconduct stand, and we will be back before the ALJ yet again shortly.

In particular, to the extent you contend to have identified only [REDACTED] you have again failed to comply with the ALJ's last order. In addition, Complainants have already admitted that [REDACTED] that representations otherwise, along with other representations in the Complaint and declarations thereto, were not true.

Moreover, your new identification of times is inconsistent with your prior discovery responses, e.g.:

- Interrogatory No. 2, which seeks identification of each product or component on which Complainants are relying for the technical prong, including to identify internal model or other nomenclature, [REDACTED]
- Interrogatory No. 68, [REDACTED]
- Interrogatory No. 82, which seeks identification by Bates number of the final versions of all documents sufficient to describe [REDACTED] on which you intend to rely for your technical prong. You have not identified documents that [REDACTED].
- Interrogatory No. 85, [REDACTED]

We have requested a telephone conference with the ALJ for next week. At that conference we will apprise the ALJ of your latest misconduct, and inform the ALJ that we have asked you to withdraw the Amended Complaint—and that if you do not, we will be pursuing appropriate sanctions under the Commission rules.

While that sanctions process unfolds, we will continue to build the record of your ongoing misrepresentations. To that end, as discussed with the ALJ, please confirm Complainants will make available a representative for deposition on December 7 regarding [REDACTED]

Regards,
Sarah

From: Kendall.Loebbaka <Kendall.Loebbaka@knobbe.com>
Sent: Tuesday, November 23, 2021 7:39 PM
To: WH Apple-Masimo 1276 Service List <WHApple-Masimo1276ServiceList@wilmerhale.com>
Cc: Masimo.AppleITC <Masimo.AppleITC@knobbe.com>
Subject: ITC No 337-TA-1276 (CBI)

EXTERNAL SENDER

[REDACTED]

Counsel,

Pursuant to ALJ Bhattacharyya's instructions at the November 19, 2021 discovery teleconference, Masimo identifies the

[REDACTED]
[REDACTED] as examples. As explained in Masimo's numerous
interrogatory responses, [REDACTED]
[REDACTED]

This list is intended to identify [REDACTED] discussed at the November 19, 2021
discovery teleconference. Masimo has identified in other interrogatory responses, including its response to
Interrogatory No. 2, [REDACTED] for the '127 patent.

REDACTED

REDACTED

Best regards,
Kendall

Kendall Loebbaka
Partner

949-721-7687 Direct

Knobbe Martens

EXHIBIT U

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

**COMPLAINANTS' FIFTH SUPPLEMENTAL RESPONSES AND OBJECTIONS TO
APPLE INC.'S FIRST SET OF INTERROGATORIES
(1-3, 32, 39-45, 48-52, 54-55, AND 57-60)**

Complainants Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Masimo" or "Complainants") hereby provides its Fifth supplemental responses and objections to Respondent Apple Inc.'s ("Apple") First Set of Interrogatories (Nos. 1-3, 32, 39-45, 48-52, 54-55, and 57-60).

PRELIMINARY STATEMENT

1. The following responses are based upon information currently available to and located by Complainants. Complainants have not completed their investigation of the facts relating to this action. Complainants reserve the right to supplement their responses to these interrogatories.

2. Complainants respond without waiving:

- a. the right to raise all questions of authenticity, relevancy, materiality, privilege, and admissibility that may arise in this or any other action including any such questions regarding any information or documents identified or provided in response to these requests;

[REDACTED]

Complainants' responses to Interrogatory No. 3 provide the information sought by this interrogatory. Complainants thus incorporate their responses to Interrogatory No. 3 as if set forth fully herein.

Discovery is ongoing. Complainants reserve the right to supplement their response to this interrogatory, for example based on additional fact discovery, expert discovery, Apple's contentions such as for invalidity or non-infringement, Apple's introduction of any additional products, and the ALJ's claim construction.

INTERROGATORY NO. 2:

Separately, for each Asserted Patent:

(a) identify, by Product name, Product code, sales code, model or part number, project development name or code, and all internal Product nomenclature, each Product or component on which Complainants rely in the Complaint or otherwise relies or will rely in support of its allegation that it satisfies the technical prong of the domestic industry requirement;

(b) separately identify the specific claims that each Product or component substantially embodies/embodyed, practices/practiced, is/was made in accordance with, or is/was used to practice;

(c) provide a detailed description of how each identified claim reads on each identified Product or component, including a chart that compares each limitation of each identified claim with each identified Product or component;

(d) identify all Persons with knowledge that support Your response to (a)–(c); and

(e) identify all Documents by Bates numbers that support Your response to (a)–(c).

CONFIDENTIAL MATERIAL UNDER SEAL REDACTED

RESPONSE TO INTERROGATORY NO. 2:

Complainants incorporate their General Objections above as set forth in full herein. Complainants object to this interrogatory to the extent that it seeks information protected by the attorney-client privilege, the attorney work product doctrine, the common interest privilege, and/or any other applicable privilege or protection. Complainants further object to this interrogatory as overly broad, unduly burdensome, and irrelevant, at least to the extent it calls for Complainants to “identify all Persons with knowledge that support Your response to (a)–(c)” and “identify all Documents by Bates numbers that support Your response to (a)–(c).” Complainants further object to this interrogatory to the extent that it calls for an expert opinion or a legal conclusion. Complainants further object to the phrases “detailed description” and “project development name or code, and all internal Product nomenclature” as vague and ambiguous. Complainants further object to this interrogatory as a premature contention interrogatory. Complainants further object to this interrogatory as compound on the grounds that it contains at least 3 discrete subparts (at least one seeking the identification of products, parts, and related codes; at least one seeking the identification of claims and a technical prong contention; at least one seeking the identity of persons; and at least one seeking the identity of documents) and thus consists of multiple interrogatories.

Subject to and without waiving their objections, Complainants respond as follows:

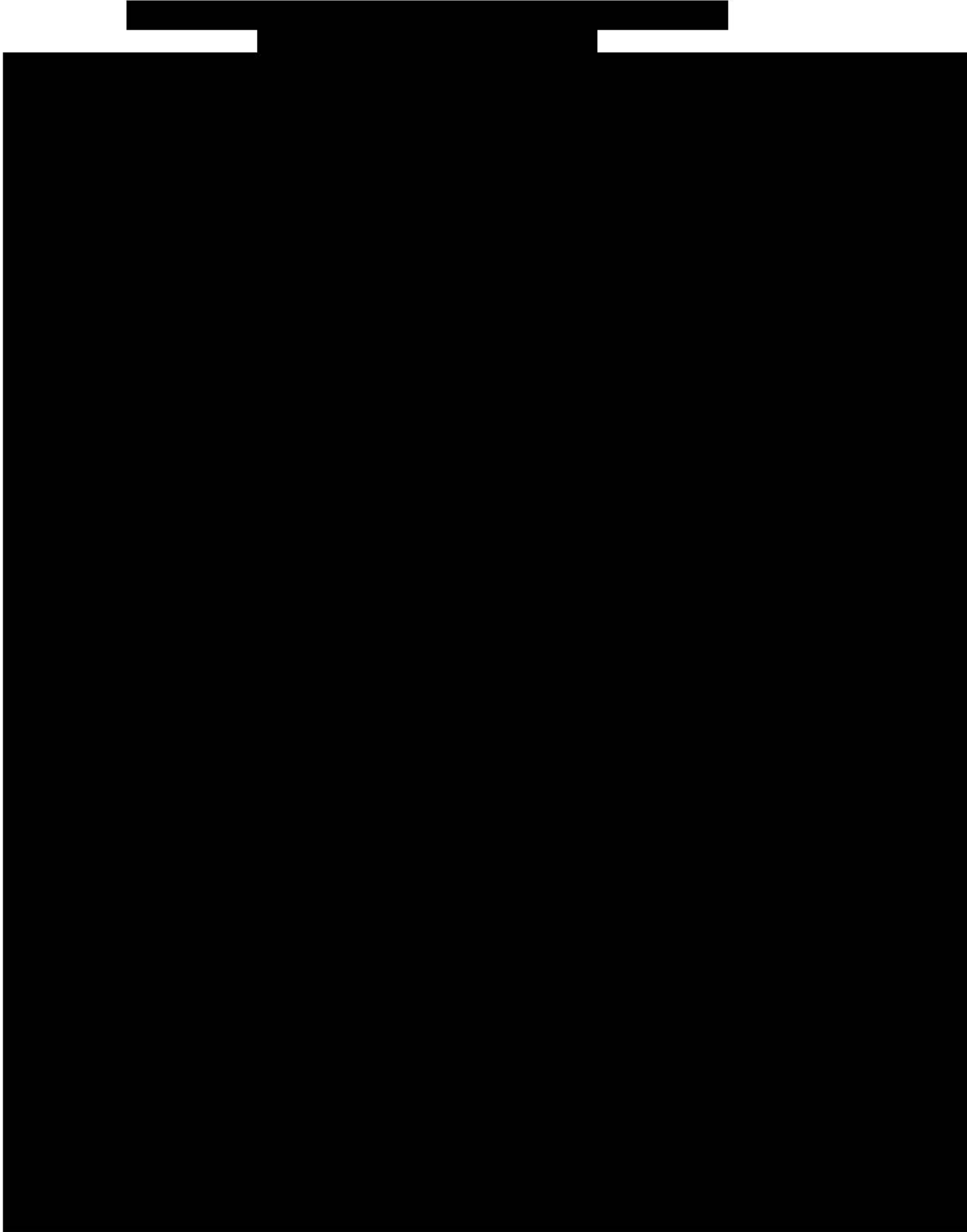
[REDACTED]

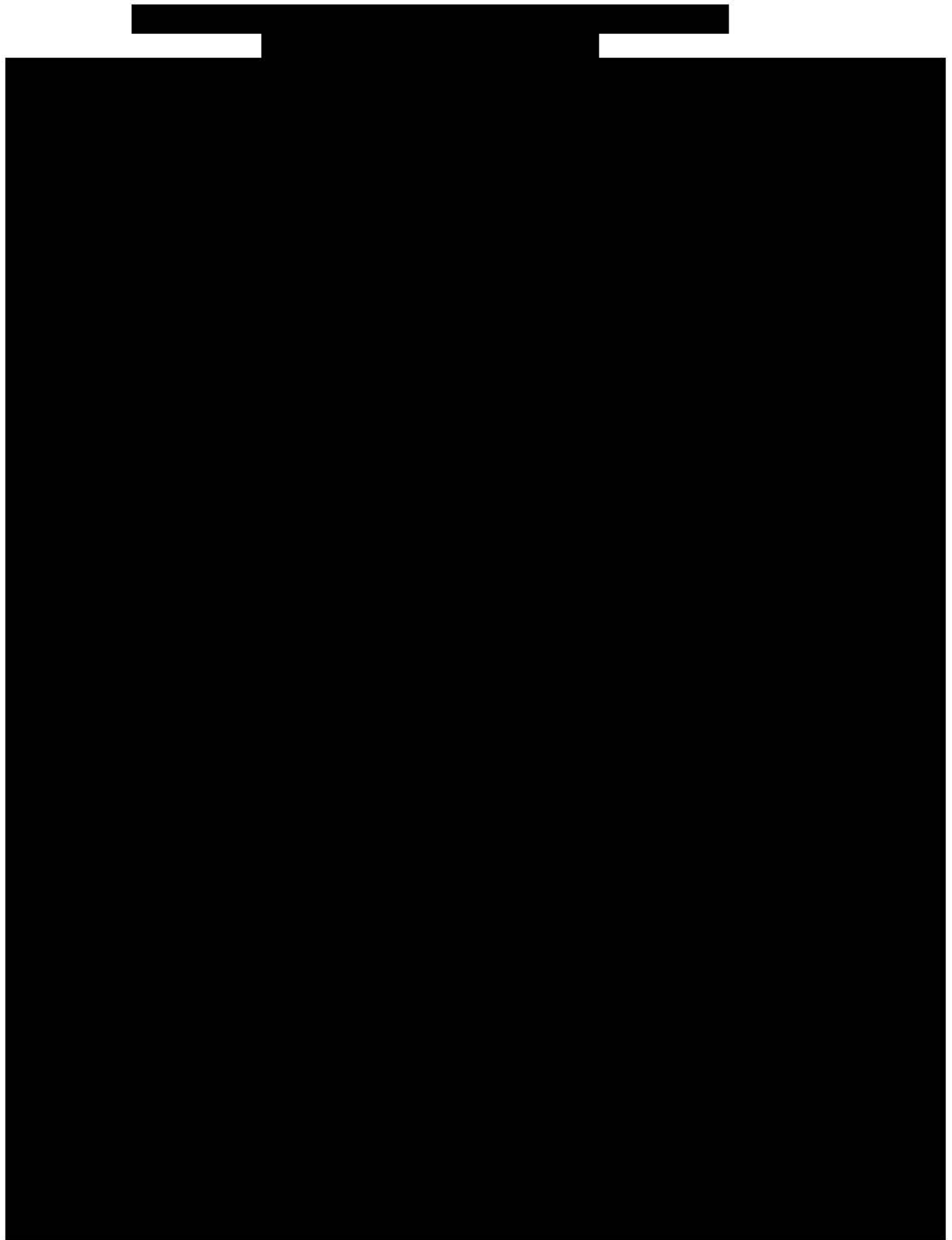
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





[REDACTED]

[REDACTED]

Complainants hereby incorporate by reference as if stated in full herein Confidential Exhibits 22-26 to the Amended Complaint, which are exemplary claim charts for the '501, '502, '648, '745, and '127 patents, respectively.

[REDACTED]

Examples of documents containing information responsive to this interrogatory, include at least the following: [REDACTED]

[REDACTED]

Discovery is ongoing. Complainants reserve the right to supplement their response to this interrogatory, for example based on additional fact discovery, expert discovery, Apple's contentions such as for invalidity or non-infringement, and the ALJ's claim construction.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 2 (9/23/2021):

Complainants incorporate their original objections and response above as if set forth in full herein. Subject to and without waiving their objections, Complainants further respond as follows:

[REDACTED]

Discovery is ongoing. Complainants reserve the right to supplement their response to this interrogatory, for example based on additional fact discovery, expert discovery, Apple's contentions such as for invalidity or non-infringement, and the ALJ's claim construction.

SECOND SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 2 (11/17/2021):

Complainants incorporate their original objections and response above as if set forth in full herein. Subject to and without waiving their objections, Complainants further respond as follows:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

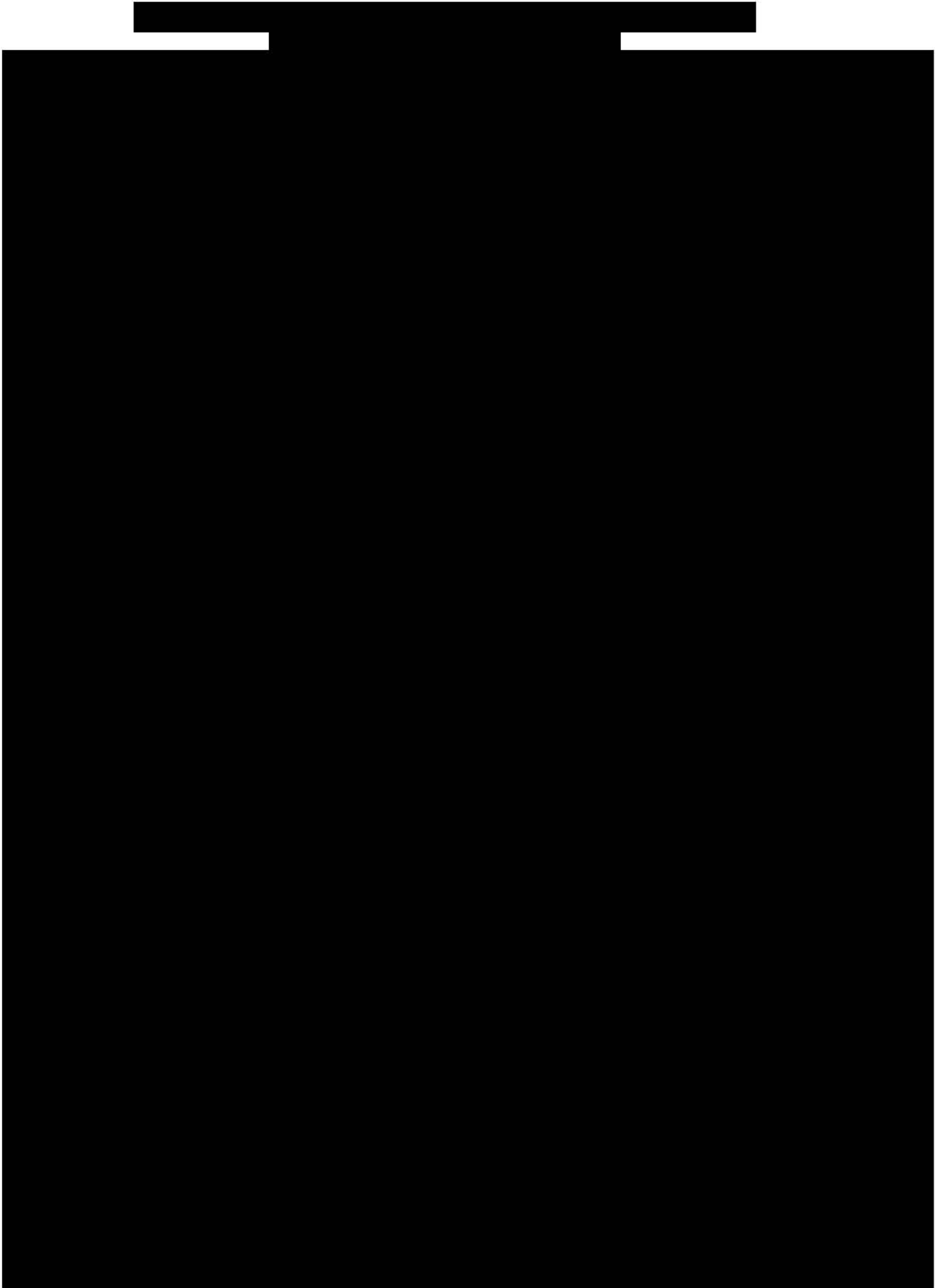
[REDACTED]

[REDACTED]

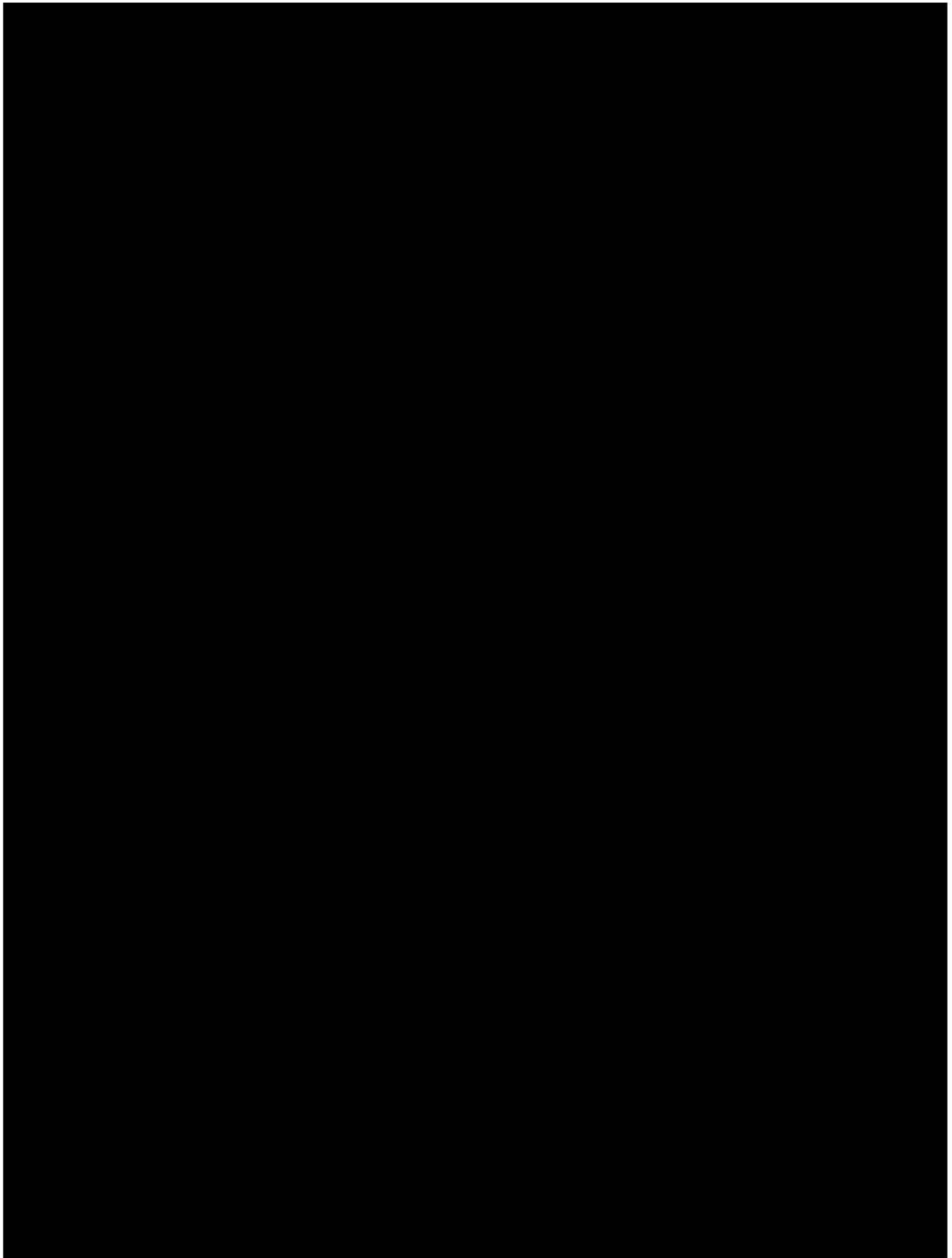
[REDACTED]

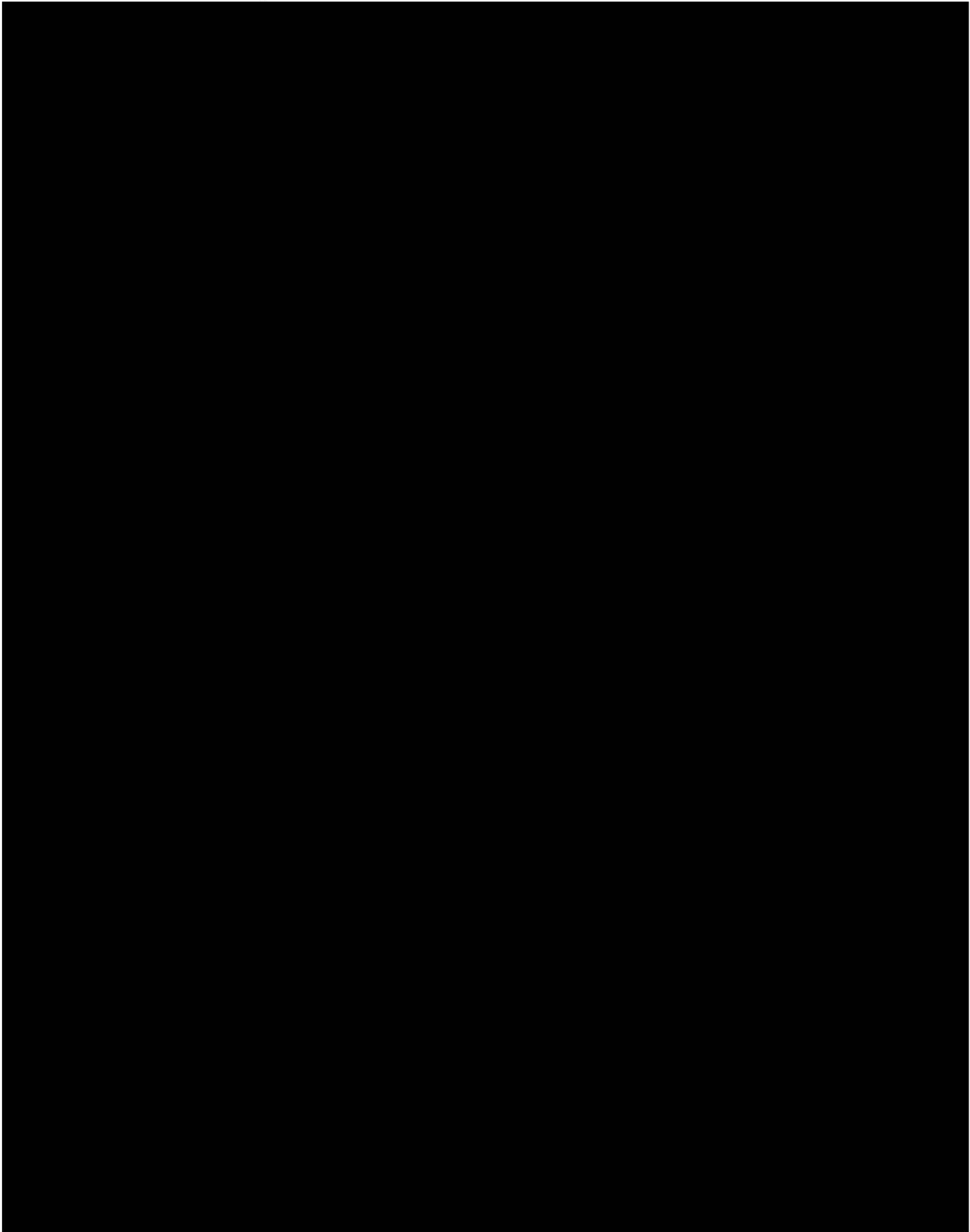
[REDACTED]

[REDACTED]



[REDACTED]





THIRD SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 2 (12/3/2021):

Complainants incorporate their original objections and response above as if set forth in full herein. Subject to and without waiving their objections, Complainants further respond as follows:

Complainants have alleged that a domestic industry exists or is in the process of being established with respect to the asserted '501, '502, '648, '745 and '127 patents. In this supplemental response, Complainants have identified [REDACTED] that satisfy the technical prong of the domestic industry requirement by practicing the identified claims of the '501, '502, '648, '745 and '127 patents.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[illegible]

[REDACTED]

[REDACTED]

To the extent any claim limitations of the Asserted Patents are not literally practiced by Complainant's patent-practicing [REDACTED] Complainants contend the limitations are practiced under the doctrine of equivalents because the identified features of the patent-practicing [REDACTED] are insubstantially different from the literal claim elements, for example because they perform substantially the same function in substantially the same way to achieve substantially the same result. Complainants' above express reservation of rights to supplement their response to this contention interrogatory includes the right to further articulate Complainants' contentions with regards to satisfaction of the technical prong under the doctrine of equivalents.

[REDACTED]

[REDACTED]

[REDACTED]

This response and the appended domestic industry claim charts (Appendices 2A-2F) comprise Complainants' initial response to this contention interrogatory. Complainants expressly reserve the right to supplement their response to this contention interrogatory, for example based on additional fact discovery, expert discovery, and the ALJ's claim construction.

Discovery is ongoing. Complainants are in no way limited to the evidence cited in the accompanying Appendices 2A-2F to demonstrate how [REDACTED] and Complainants' express reservation of rights to supplement their response to this contention interrogatory includes the right to identify additional documents, information, and things supporting Complainants' domestic industry contentions as discovery progresses and this Investigation continues. Complainants reserve the right to supplement their

[REDACTED]

response to this interrogatory, for example based on additional fact discovery, expert discovery, Apple's contentions such as for invalidity or non-infringement, Apple's responses to the information described in response to this interrogatory, Complainants' introduction of any additional products, and the ALJ's claim construction.

INTERROGATORY NO. 3:

Separately for each claim and Product, apparatus, or method identified in response to Interrogatory No. 1, state the complete legal and factual basis for Complainants' allegation of infringement. In Your response, You should, include, without limitation:

- (a) state the date that each Complainant first became aware of the alleged infringement by Respondent;
- (b) describe in detail the circumstances surrounding awareness, testing, inspection, or evaluation of the alleged infringement by Respondent by or on behalf of either Complainant;
- (c) state whether Complainants contend that Respondent's alleged infringement is direct infringement, induced infringement, and/or contributory infringement, and if Complainants contend that Respondent's alleged infringement is indirect, identify any direct infringement and Respondent's acts that Complainants contend induce or contribute to that direct infringement;
- (d) state whether Complainants contend that the Product infringes at the time of importation;
- (e) provide a chart comparing each element, limitation, or step of the claim to the structure or function of the Product that Complainants contend satisfies that element, limitation, or step of the claim, including whether the Product satisfies the element, limitation, or step literally, under the doctrine of equivalents, or both;

UNITED STATES INTERNATIONAL TRADE COMMISSION

In the Matter of:)	Investigation No.
CERTAIN LIGHT-BASED PHYSIOLOGICAL)	337-TA-1276
MEASUREMENT DEVICES AND)	
COMPONENTS THEREOF)	

Pages: 1 through 105
Place: Washington, D.C.
Date: February 17, 2022

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1 UNITED STATES INTERNATIONAL TRADE COMMISSION

2 Washington, D.C.

3 BEFORE THE HONORABLE MONICA BHATTACHARYYA

4 Administrative Law Judge

5 _____

6 In the Matter of:) Investigation No.

7 CERTAIN LIGHT-BASED PHYSIOLOGICAL) 337-TA-1276

8 MEASUREMENT DEVICES AND)

9 COMPONENTS THEREOF)

10 _____

11

12 Remote Hearing

13

14 International Trade Commission

15 500 E Street, S.W.

16 Washington, D.C.

17

18 Thursday, February 17, 2022

19

20 TUTORIAL AND MARKMAN HEARING - REMOTE

21

22 The Hearing commenced remotely, pursuant to the

23 notice of the Judge, at 9:30 a.m. EST.

24

25 Reported by: Karen Brynteson, FAPR, RMR, CRR

1 APPEARANCES:

2 ** All parties appearing telephonically **

3

4 FOR COMPLAINANTS MASIMO CORPORATION and CERACOR
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12 Attorney-Advisor

13 U.S. International Trade Commission

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1 P R O C E E D I N G S

2 (9:30 a.m.)

3 JUDGE BHATTACHARYYA: Good morning, everyone.

4 (A chorus of good mornings.)

5 JUDGE BHATTACHARYYA: Let's go on the public -- on
6 the record. We're on the public record. We're here for
7 the technology tutorial and Markman hearing in
8 Investigation 337-TA-1276, Certain Light-Based
9 Physiological Measurement Devices and Components Thereof.

10 This is Monica Bhattacharyya, Presiding ALJ.
11 And with me is my attorney advisor, Ted Jou. Could we
12 please have appearances from counsel.

13 MS. SWAROOP: Good morning, Your Honor. This is
14 Sheila Swaroop for Complainants. Also attending with me
15 today is Irfan Lateef, who is here with me, as well as
16 Joseph Re, who is also on your screen.

17 JUDGE BHATTACHARYYA: Good morning.

18 MR. MUELLER: And good -- I'm sorry. Good
19 morning, Your Honor. This is Joe Mueller on behalf of the
20 Respondent. And my colleagues Sarah Frazier, Mark Selwyn,
21 and Cindy Vreeland are going to handle the bulk of the
22 arguments today, Your Honor, but before they do, I just
23 want to briefly raise a couple issues.

24 Your Honor, we will, of course, proceed with
25 this hearing and continue to diligently litigate this case

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

**ORDER NO. 25: INITIAL DETERMINATION GRANTING COMPLAINANTS'
UNOPPOSED MOTION FOR PARTIAL WITHDRAWAL OF
CERTAIN CLAIMS**

(March 23, 2022)

On March 22, 2022, Complainants Masimo Corporation and Cercacor Laboratories, Inc. filed a motion (1276-030) to withdraw its allegations of infringement with respect to claims 2, 4, 5, 7, 11, 16, 19, 20, and 22-30 of U.S. Patent No. 10,912,501 (“the ’501 patent”), claims 1-2, 4-6, 8-12, 14-18, 20, 25, and 26 of U.S. Patent No. 10,912,502 (“the ’502 patent”), claims 3, 4, 6, 7, 9, 10, 13-17, 19, 22, and 25-28 of U.S. Patent No. 10,945,648 (“the ’648 patent”), claims 1, 3-6, 8, 11, 14, 20-24, and 26 of U.S. Patent No. 10,687,745 (“the ’745 patent”), and claims 7 and 8 of U.S. Patent No. 7,761,127 (“the ’127 patent”). Respondent Apple Inc. does not oppose Complainants’ withdrawal of these allegations. *See* Motion at 5.


Commission Rule 210.21(a)(1) provides that “[a]ny party may move at any time prior to the issuance of an initial determination on violation of section 337 of the Tariff Act of 1930 to terminate an investigation in whole or in part as to any or all respondents, on the basis of withdrawal of the complaint or certain allegations contained therein” 19 C.F.R. § 210.21(a)(1). The Commission has held that “in the absence of extraordinary circumstances, termination of an investigation will be readily granted to a complainant during the prehearing

stage of an investigation.” *Certain Ultrafiltration Membrane Systems, & Components Thereof Including Ultrafiltration Membranes*, Inv. No. 337-TA-107, Comm’n Action & Order at 2 (Mar. 11, 1982).

In compliance with Commission Rules, the motion states that other than discovery stipulations, “there are no agreements, written or oral, express or implied between the parties concerning the subject matter of the investigation.” Motion at 4. Complainants submit that the narrowing of the asserted claims will simplify the issues in the investigation and conserve judicial resources. *Id.* at 3. The undersigned finds that the motion complies with Commission Rule 210.21(a)(1), and there are no extraordinary circumstances preventing the withdrawal of the identified allegations.

Accordingly, the motion (1276-030) is hereby GRANTED, and it is the undersigned’s initial determination that the identified allegations of infringement shall be terminated from the investigation.¹ Pursuant to Commission Rule 210.42(h), this initial determination shall become the determination of the Commission unless a party files a petition for review of the initial determination pursuant to Commission Rule 210.43(a), or the Commission, pursuant to Commission Rule 210.44, orders, on its own motion, a review of the initial determination or certain issues contained herein. 19 C.F.R. § 210.42(d).

SO ORDERED.


Monica Bhattacharyya
Administrative Law Judge

¹ The asserted claims remaining in the investigation are claims 1, 3, 6, 8, 9, 12-15, 17, 18, and 21 of the ’501 patent; claims 19, 21, 22, 24, and 28-30 of the ’502 patent; claims 1, 2, 5, 8, 11, 12, 20, 21, 23, 24, 29, 30 of the ’648 patent; claims 2, 9, and 27 (and claim 18 for domestic industry) of the ’745 patent; and claim 9 of the ’127 patent. *See* Motion at 3.

Certain Light-Based Physiological Measurement Devices and Components Thereof; Inv. 337-1276 Violation
No. 337-TA-1276 (Violation)

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached document has been served via EDIS upon the Commission OUII Investigative Attorney and the following parties as indicated, upon the date listed below.

Document	Security	Document Type	Official Rec'd Date	Title
766184	Public	ID/RD - Other Than Final on Violation	03/23/2022 09:51 AM	Initial Determination Granting Complainants' Unopposed Motion for Partial Withdrawal of Certain C...

Service Date: March 23, 2022

/s/

Lisa R. Barton
U.S. International Trade Commission
500 E Street, S.W.
Suite 112
Washington, D.C. 20436

APPX13047
ENTIRELY REDACTED

APPX13067-13069
ENTIRELY REDACTED

UNITED STATES INTERNATIONAL TRADE COMMISSION**Washington, D.C.****In the Matter of****CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF****Inv. No. 337-TA-1276****ORDER NO. 31: DENYING RESPONDENT'S MOTION FOR SANCTIONS**

(April 28, 2022)

On December 28, 2021, Respondent Apple Inc. ("Apple") filed a motion (the "Motion for Sanctions," Docket No. 1276-012) for sanctions against Complainants Masimo Corporation ("Masimo") and Cercacor Laboratories, Inc. ("Cercacor"), attaching exhibits ("Apple Exhibits") and a memorandum in support ("Apple Memo."). On January 10, 2022, Complainants filed a response in opposition to the motion ("Opposition"), attaching exhibits ("Masimo Exhibits"). On January 12, 2022, Apple filed a reply brief ("Reply").

On February 16, 2022, Apple filed a motion (the "Supp. Motion," Docket No. 1276-021) for leave to file a notice of supplemental facts regarding the Motion for Sanctions, attaching supplemental exhibits ("Supp. Exhibits"), including the deposition transcript of Joe Kiani, Masimo's Chief Executive Officer. Supp. Exhibit B. On February 28, 2022, Complainants filed an opposition to the Supplemental Motion ("Supp. Opp."), attaching supplemental exhibits ("Supp. Opp. Exhibits"). On March 3, 2022, Apple filed a reply in support of the Supplemental Motion ("Supp. Reply").¹

¹ The undersigned finds that the supplemental exhibits include information that is relevant and could not have been provided in the original Motion for Sanctions. Accordingly, the Supplemental Motion (1276-021) is hereby GRANTED.

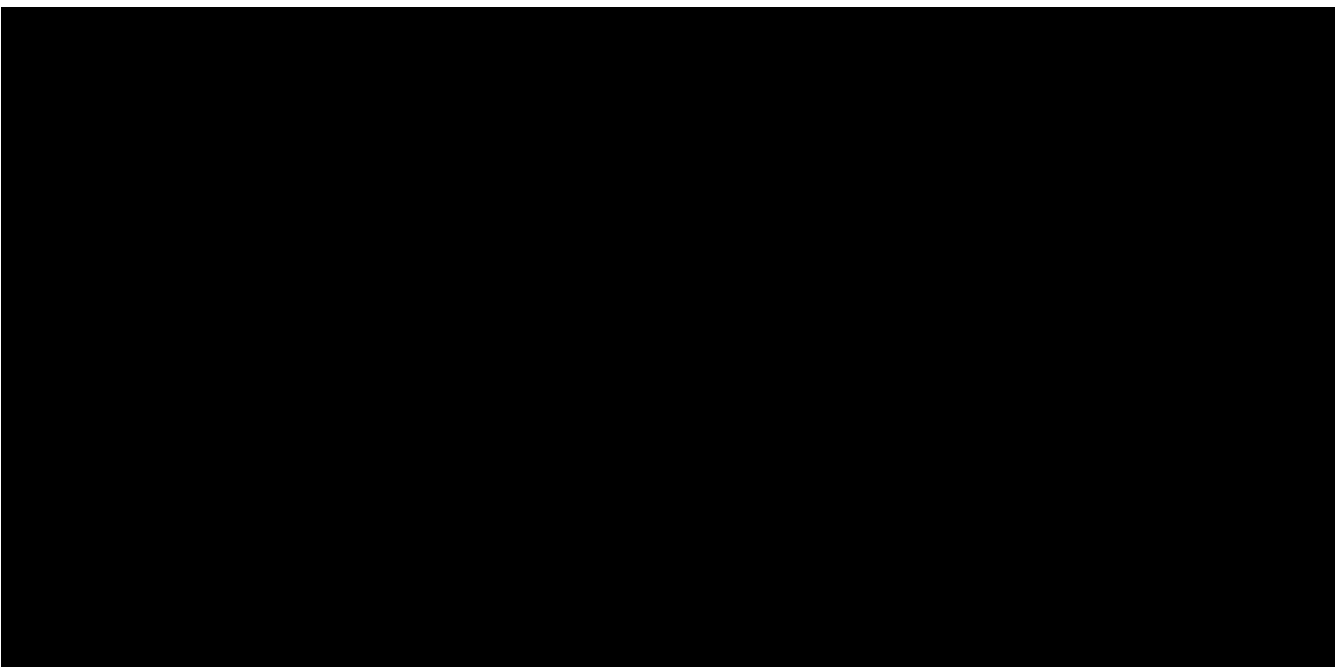
CONFIDENTIAL MATERIAL FILED UNDER SEAL REDACTED

I. BACKGROUND

Complainants filed their Amended Complaint on July 7, 2021, identifying a “Masimo Watch—[REDACTED] as the alleged domestic industry product for four of the five asserted patents. Amended Complaint at ¶ 86, EDIS Doc. ID 746514 (July 7, 2021).

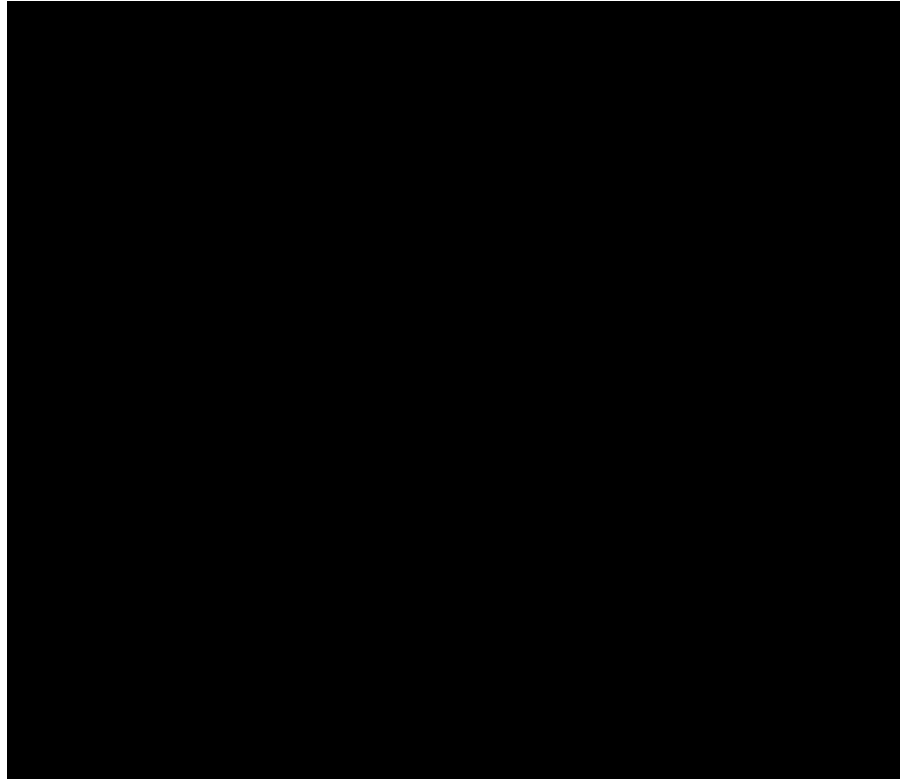
Complainants represented that “[a] confidential sample of a Masimo Watch that embodies the claims of the [Asserted] Patent[s] is available upon request.” *Id.* at ¶¶ 47, 54, 61, 68. Attached to the Amended Complaint is a declaration from Bilal Muhsin, the Chief Operating Officer of Masimo, representing that “[t]he Masimo Watch Product is a watch developed by Masimo and [REDACTED]

[REDACTED] and that “Masimo [REDACTED] [REDACTED] Amended Complaint, Exhibit 27 at ¶ 4. He describes the functionality of the “Masimo Watch Product” and represents that claim charts attached to the Amended Complaint “accurately reflect the design of the Masimo Watch Product.” *Id.* at ¶¶ 4-23. Mr. Muhsin’s declaration [REDACTED] of the “Masimo Watch,” which were attached to the Amended Complaint as Exhibit 21. *Id.* at ¶ 8.



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Amended Complaint, Exhibit 21. Claim charts attached to the Amended Complaint rely on the [REDACTED] of a “Masimo Watch” product.



See Amended Complaint, Exhibit 22 at 9, Exhibit 23 at 11, Exhibit 24 at 22.

In discovery, Apple sought production of a sample of the “Masimo Watch.” *See* Apple Exhibit A (Request for Production No. 124). After extensive discussions between the parties, Complainants agreed to make certain “Masimo Watch” products available for inspection. *See* Apple Exhibit B, Exhibit C, Exhibit D, Exhibit E, Exhibit F, Exhibit G, Exhibit H, Exhibit I. Complainants produced [REDACTED] physical items for inspection on October 20, 2021, including a [REDACTED] of the Masimo Watch.” Apple Exhibit I. Apple sought to compel the production of a “Masimo Watch” [REDACTED], and the parties participated in a teleconference with the undersigned on October 28, 2021. *See* Teleconference Transcript (Oct. 28, 2021), EDIS Doc. ID 755884/755885. On November 10, 2021, Complainants produced [REDACTED] physical objects for inspection. *See* Apple Exhibit M (photograph

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from 11/10/21 inspection), Exhibit N (email discussion regarding inspection), Exhibit O (chart listing items for inspection).

The parties discussed the second inspection of “Masimo Watch” products during a subsequent teleconference on November 19, 2021. *See* Teleconference Transcript (Nov. 19, 2021), EDIS Doc. ID 757325. During this teleconference, Complainants were ordered to identify which of the physical objects provided for inspection they intended to rely on for the technical prong of the domestic industry requirement. *Id.* at 25-27. Complainants provided an identification on November 23, 2021. Apple Exhibit N. The parties again discussed the “Masimo Watch” physical exhibits during a teleconference on December 6, 2021. *See* Teleconference Transcript (Dec. 6, 2021), EDIS Doc. ID 758034.

On December 15, 2021, Complainants produced a physical “Masimo Watch” (labeled MASITC_P_127) in connection with the deposition of Bilal Muhsin. *See* Apple Exhibit S at 1 (Dec. 14 email), Exhibit T (Muhsin Dep. Tr.) at 6:2-8:1. Masimo represented that “[t]he physical [REDACTED] Apple Exhibit S at 1 (Dec. 13 email); *see also* Exhibit T at 46:16-18 (describing the “physical [REDACTED] [REDACTED]. Mr. Muhsin [REDACTED]. *See* Apple Exhibit T at 35:3-36:17, 44:23-45:5. Complainants’ counsel represented that the physical sample [REDACTED] [REDACTED]. *Id.* at 46:6-8.

In [REDACTED], Masimo manufactured a “Masimo Watch” product and Complainants produced a sample of this product to Apple at the deposition of Masimo employee Stephen Scruggs on January 6, 2022. *See* Opposition at 19; Masimo Exhibit 59; Supp. Opp. at 2, Physical Exhibit A. Apple took the deposition of Masimo CEO Mr. Kiani on February 11, 2022, where he discussed the development of the “Masimo Watch.” Supp. Exhibit B.

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II. BRIEFING

Apple moves for sanctions against Complainants based on alleged misrepresentations in the Amended Complaint. Apple Memo. at 28-42. In particular, Apple identifies Complainants' representations that a physical "Masimo Watch" [REDACTED], describing a "Masimo Watch—[REDACTED]" and stating that "[a] confidential sample of a Masimo Watch . . . is available upon request." Amended Complaint at ¶¶ 47, 54, 61, 68, 86. Apple also cites the declaration of Mr. Muhsin attached to the Amended Complaint, which describes "the design of the Masimo Watch Product." Amended Complaint, Exhibit 27 at ¶¶ 4-23. Apple argues that the statements in the Amended Complaint "make crystal clear that the Complainants allege the existence of a [REDACTED] [REDACTED] Apple Memo. at 31.

Apple contends that the representations in the Amended Complaint regarding the "Masimo Watch" were untrue based on evidence that was uncovered during discovery. Apple Memo. at 32-42. Apple submits that none of the physical items that Complainants made available for inspection [REDACTED] [REDACTED]. *Id.* at 32-36. Apple further identifies evidence that no "Masimo Watch" [REDACTED] [REDACTED]. *Id.* at 36. Apple argues that Complainants' inconsistent conduct during discovery is further evidence that the statements in the Amended Complaint regarding the "Masimo Watch" were false. *Id.* at 37-39. Apple submits that the appropriate sanctions in this case are termination of the investigation and the payment of Apple's attorneys' fees and costs. *Id.* at 39-42.

Complainants oppose the motion for sanctions, arguing that Apple's contentions are premised on an erroneous assumption that the domestic industry requirement requires a finished

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commercial product. Opposition at 28-32. Complainants submit that the Amended Complaint did not allege the existence of a [REDACTED] [REDACTED] *Id.* (citing Amended Complaint at ¶ 89). Complainants submit that numerous physical “Masimo Watch” articles [REDACTED] and were produced for inspection during discovery. *Id.* at 33. Complainants submit that a [REDACTED] of the “Masimo Watch” [REDACTED], showing that the representation in the Amended Complaint regarding a [REDACTED] was accurate. *Id.* at 34-37. Complainants argue that sanctions are not appropriate in these circumstances and the scope of Apple’s requested relief is unwarranted. *Id.* at 37-39. Complainants suggest that the Administrative Law Judge should consider sanctions against Apple for its discovery conduct and allegedly false statements in the Motion for Sanctions. *Id.* at 39-42.²

In reply, Apple contends that it is “clear from the Complaint itself” that “the Complaint was intended to convey the existence of a [REDACTED].” Reply at 4-5. Apple submits that Complainants’ statements have been shown to be false, because no [REDACTED] “Masimo Watch” that [REDACTED]. *Id.* at 5. Apple argues that Complainants have identified no evidence from before the filing of the Amended Complaint that shows [REDACTED]. *Id.* at 5-6. Apple submits that it clearly requested a sample of the “Masimo Watch” in discovery and that Complainants unreasonably delayed their production of physical items. *Id.* at 7-8.³

² Complainants’ request for *sua sponte* sanctions against Apple circumvents the notice requirements under Commission Rule 210.4(d)(1). The undersigned will not consider Complainants’ request in the context of this order.

³ Although Apple makes numerous allegations regarding Complainants’ conduct during discovery, the motion does not seek discovery-based sanctions. *See* Apple Mot. at 1-4; Memo. at 36 n.11.

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In its supplemental brief, Apple cites evidence that the “Masimo Watch” [REDACTED]

[REDACTED] See Supp. Exhibit B. In opposition, Complainants argue that [REDACTED]

[REDACTED] Supp. Opp. at 1-2. Complainants identify the testimony of a Masimo engineer explaining that a “Masimo Watch” device [REDACTED]

Supp. Opp. Exhibit 68 (Ali-Ali Dep. Tr.) at 89-90, 124-25. In reply, Apple cites testimony from another Masimo engineer that [REDACTED]

[REDACTED] See Motion Exhibit B (Scruggs Dep. Tr.) at 34-35.

III. LEGAL STANDARDS

Commission Rule 210.4 places an obligation on parties making representations before the Commission to certify “to the best of the person’s knowledge, information, and belief, formed after an inquiry reasonable under the circumstances” that:

- (1) [The submission] is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceeding;
- (2) The claims, defenses, and other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; [and]
- (3) The allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

19 C.F.R. § 210.4(c). When these obligations have been violated, the administrative law judge may “impose an appropriate sanction upon the attorneys, law firms, or parties that have violated paragraph (c) or are responsible for the violation.” 19 C.F.R. § 210.4(d). “If any portion of a representation is found to be false, frivolous, misleading, or otherwise in violation of paragraph

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(c), a sanction may be imposed.” *Id.* “In determining whether paragraph (c) has been violated, the administrative law judge or the Commission will consider whether the representation or disputed portion thereof was objectively reasonable under the circumstances.” *Id.*

Commission Rule 210.4(d)(1)(i) provides that a party may seek sanctions by motion. 19 C.F.R. § 210.4(d)(1)(i). The burden of proving a violation of Commission Rule 210.4(c) rests with the party moving for sanctions. *See Certain Wind and Solar-Powered Light Posts*, Inv. No. 337-TA-746, Order No. 13 at 9, EDIS Doc. ID 451418 (May 11, 2011) (citing *Certain Self-Inflating Mattresses*, Inv. No. 337-TA-302, Recommended Determination at 7-8, 1990 WL 710471 (Dec. 24, 1990)).

IV. DISCUSSION

In consideration of the parties’ arguments, the undersigned finds that sanctions are not warranted under Commission Rule 210.4(d). Although the Amended Complaint contains statements regarding the “Masimo Watch” that are susceptible to different interpretations, Apple has not shown Complainants’ representations to be false, frivolous, or misleading.

Apple reads the Amended Complaint to assert the existence of a [REDACTED] “Masimo Watch,” but the undersigned agrees with Complainants that the Amended Complaint, when read as a whole, describes a “Masimo Watch” that [REDACTED]

[REDACTED] The Amended Complaint states that “Masimo [REDACTED]
[REDACTED].” Amended Complaint at ¶ 86. [REDACTED]

[REDACTED] *Id.* at ¶ 88. With respect to the patents where Complainants are relying on the “Masimo Watch” for a domestic industry, the Amended Complaint is equivocal on the issue of whether a domestic industry exists or is in the process of being established: “To the extent it is

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determined that a domestic industry [REDACTED]

[REDACTED] *Id.*

at ¶ 86. In view of these statements, it is clear that the subsequent statement—“the Masimo Watch is protected by one or more claims of [the asserted patents]”—refers to a product that is [REDACTED]. *See id.* The undersigned finds that it is objectively reasonable to read the Amended Complaint to refer to a “Masimo Watch” that [REDACTED].⁴

Apple fails to identify any statement in the Amended Complaint explicitly representing that the “Masimo Watch” [REDACTED]. An Administrative Law Judge addressed a similar situation in *Certain Blu-Ray Disc Players, Components Thereof and Products Containing Same*, where a motion for sanctions was denied with respect to a declaration regarding a complainant’s domestic industry where the parties disputed certain statements. Inv. No. 337-TA-824, Order No. 36 at 5-6, EDIS Doc. ID 499178 (Dec. 5, 2012). In that case, the Administrative Law Judge found that “Respondents are misreading or misinterpreting those statements to support the motion for sanctions” and “failed to show that [the declarant] made any false, material statements in his declaration.” *Id.* In the present motion, Apple has misread the Amended Complaint to represent that the “Masimo Watch” was a [REDACTED]

⁴ The Commission has recognized the possibility that a domestic industry might be shown to be in the process of being established while the development of protected articles is ongoing. *See Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing Same*, Inv. No. 337-TA-1073, Comm’n Op. at 11-13, EDIS Doc. ID 684974 (July 19, 2019) (“The development of protected articles is one aspect of the process of establishing a domestic industry relating to such articles.”); *see also Certain Non-Volatile Memory Devices and Products Containing the Same*, Inv. No. 337-TA-1046, Comm’n Op. at 41-44, EDIS Doc. ID 659979 (Oct. 26, 2018) (recognizing that commercial production of domestic industry articles is not required).

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[REDACTED] and has identified two allegedly false statements in the Amended Complaint—Complainants’ representations that the “Masimo Watch” is [REDACTED] and that a “confidential sample of a Masimo Watch that embodies the claims of the [asserted patents] is available upon request.” *See* Amended Complaint at ¶¶ 47, 54, 61, 68, 86. As discussed below, Apple has not shown that either of these statements lacks evidentiary support.

With respect to the [REDACTED], neither party has identified clear evidence of Masimo’s [REDACTED]. A Masimo internal presentation submitted by Apple identifies [REDACTED]

[REDACTED] Apple Exhibit FF at 11.⁵ [REDACTED]

[REDACTED] *See* Apple Memo. at 24. Mr. Muhsin testified at his deposition that the “Masimo Watch” [REDACTED]

[REDACTED] Apple Exhibit T (Muhsin Dep. Tr.) at 8:19-22. Mr. Kiani later confirmed that [REDACTED]

[REDACTED]. Supp. Exhibit B at 121-26. Apple submits that there is no evidence that [REDACTED]

[REDACTED] *See* Reply at 5-6. Although the evidence does not show that [REDACTED]

[REDACTED] the

undersigned finds that the internal presentation and the testimony of Mr. Muhsin and Mr. Kiani

⁵ A replacement for this exhibit including a confidentiality designation was separately filed on January 7, 2022.

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are sufficient evidentiary support for the allegation that the “Masimo Watch” was [REDACTED]

[REDACTED] In particular, the internal Masimo presentation includes [REDACTED]

[REDACTED] See Apple Exhibit FF at 11 [REDACTED]

[REDACTED] Apple has interpreted the statement in the Amended Complaint to refer to a [REDACTED]

[REDACTED] In the context of the Amended Complaint, the statement can be read to be consistent with a [REDACTED], and there is sufficient evidentiary support for this allegation.⁷

With respect to the “Masimo Watch” samples that were referenced in the Amended Complaint, there is no dispute that multiple “Masimo Watch” physical items [REDACTED]

[REDACTED] As discussed above, Apple has misinterpreted the Amended Complaint to represent that there was a [REDACTED] “Masimo Watch.” Apple argues that in the absence of a [REDACTED] “Masimo Watch,” however, none of Masimo’s physical items embodied the claims of the asserted patents. In response, Complainants submit that certain [REDACTED]

[REDACTED] See Apple Exhibit J (Response to Interrogatory No. 74) at 5 (Dec. 3, 2021),

⁶ A [REDACTED]

[REDACTED] See Apple Memo. at 24 n.8. At his deposition, Mr. Muhsin [REDACTED]

[REDACTED] See Masimo Exhibit 35 at 188:20-189:17.

⁷ The undersigned has made no determination as to what a preponderance of the evidence will show with respect to whether Masimo’s plans for the “Masimo Watch” satisfy the requirements for establishing a domestic industry in the process of being established. The relevant issue on this motion is only whether there is sufficient evidentiary support for Masimo’s allegations such that sanctions are not warranted.

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Exhibit X (Response to Interrogatory No. 86) at 22 (Dec. 23, 2021). Mr. Muhsin testified that [REDACTED]

[REDACTED]
[REDACTED] Masimo Exhibit 35 (Mushin Dep. Tr.) at 26-28. Mr. Ali-Ali corroborated this testimony. *See* Supp. Opp. Exhibit 68 (Ali-Ali Dep. Tr.) at 89-90, 124-25. Apple has identified several reasons to question Complainants’ contentions regarding the [REDACTED] “Masimo Watch” physical items—Complainants have not been able to identify [REDACTED]

[REDACTED]
[REDACTED] *See* Apple Memo. at 37-39.⁸ Nevertheless, the undersigned finds that the production of physical items, [REDACTED]

[REDACTED]
[REDACTED] are sufficient evidentiary support for Complainants’ representation in the Amended Complaint that “Masimo Watch” samples could have been made available.⁹

Apple’s motion relies heavily on the precedent in *Certain Concealed Cabinet Hinges*, where the Commission terminated an investigation based on a Complainant’s false and materially misleading representations regarding its domestic industry. *See* Inv. No. 337-TA-289, Comm’n Op., 12 ITRD 1841, 1990 WL 10608981, at *1-8 (Jan. 8, 1990); Apple Memo. at 39-40. The Commission determined that sanctions were warranted in *Concealed Cabinet Hinges* where, *inter alia*, the “domestic industry allegations were made with conflicting personal knowledge on the part of both [complainant] and counsel for complainant,” complainant gave conflicting testimony regarding whether domestic industry products were assembled in the

⁸ Apple characterizes Complainants’ behavior as “discovery misconduct,” but the present motion does not seek discovery sanctions. *See supra* n.3.

⁹ The undersigned has made no determination as to what a preponderance of the evidence will show with respect to whether a “Masimo Watch” satisfying the technical prong of the domestic industry requirement for any asserted patent existed at the relevant time. The relevant issue on this motion is only whether there is sufficient evidentiary support for Masimo’s allegations such that sanctions are not warranted.

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United States, and complainant “admitted to performing little or no prefiling inquiry” regarding assembly in the United States.” *Id.* at *5. As discussed above, Apple has not made a similar showing with respect to the disputed statements in the Amended Complaint. While there is mixed evidence regarding the [REDACTED] “Masimo Watch,” Apple has not shown that Complainants’ representations in the Amended Complaint lack evidentiary support, and accordingly, no sanctions are warranted.

V. CONCLUSION

For the reasons discussed above, Apple’s motion for sanctions (1276-012) is hereby DENIED.

This order has been issued with a confidential designation. Within seven days of the date of this document, the parties shall submit a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit a single proposed public version of this order with any proposed redactions in the manner specified by Ground Rule 1.9. To the extent possible, the proposed redacting should be made electronically, in a PDF of the issued order, using the “Redact Tool” within Adobe Acrobat, wherein the proposed redactions are submitted as “marked” but not yet “applied.” The submission shall be made by email to Bhattacharyya337@usitc.gov and need not be filed with the Commission Secretary.

SO ORDERED.


Monica Bhattacharyya
Administrative Law Judge

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

Certificate of Service – Page 1

CONFIDENTIAL CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served upon the following parties as indicated, on **April 28, 2022**.



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

**On Behalf of Complainants Masimo Corporation and
Cercacor Laboratories, Inc.:**

Joseph R. Re, Esq.
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- ☐ Via Hand Delivery
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- ☐ Via First Class Mail
- ☒ Other: Email Notification
of Availability for Download

On Behalf of Respondent Apple Inc.:

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- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☐ Via First Class Mail
- ☒ Other: Service to Be
Completed by Complainants

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

**In the Matter of
CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S CORRECTED PRE-HEARING BRIEF

Lumidigm discloses a sensor that has all the features of the asserted Poeze claims. Lumidigm has multiple light sources, detectors, and a processor for performing monitoring functions, including “liveness” and traditional physiological measurements. *See, e.g.*, RX-0411 [Lumidigm] at Abstract, 3:9-34, 4:20-29. Lumidigm explains that its sensor can include any number and arrangement of light sources, including LEDs, in any of a variety of wavelengths. *Id.* at 6:38-54, 9:42-45, 9:52-55, 9:32-34. Lumidigm further confirms that the sensor can include any number and any arrangement of detectors, including “a single element, a plurality of discrete elements, or a one-or-two dimensional array of elements.” *Id.* at 6:54-58, 9:42-45, 9:52-55; 9:32-34. Lumidigm inventor Dr. Rowe confirmed that the Lumidigm inventors did not view their sensor’s use of multiple LEDs and multiple detectors as inventive. Rowe Tr. at 37:15-21.

Lumidigm also confirms that the head of its sensor (i.e., the part in contact with the user’s tissue) can have a “compound curvature on the optical surface to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 [Lumidigm] at 7:58-63. Dr. Rowe noted that such a sensor head would have a dome-shaped convex protrusion. Rowe Tr. at 69:22-70:16. Lumidigm’s sensor also includes other standard components including, for example, power conditioning and signal processing electronics (e.g., RX-0411 [Lumidigm] at 6:20-37), internal processors and memory for calculating and storing measurements (e.g., *id.* at 12:56-13:14), and interfaces for wireless communications (e.g., *id.* at Fig. 8E, 13:9-12).

Lumidigm also discloses that the sensor can be incorporated into a “portable electronic device” and provides as exemplary devices: cellphones, personal digital assistants, key fobs, and user-worn watches. RX-0411 [Lumidigm] at 3:35-37. Lumidigm discloses a wristwatch in Figure

8B and explains that “any of the sensor geometries previously disclosed or other equivalent configurations” can be used in its wristwatch implementation. *Id.* at 11:54-12:2.

As discussed below, Lumidigm alone anticipates claims 12 of the ’501 patent, 22 of the ’502 patent, 12, 24, and 30 of the ’648 patent and/or at a minimum alone renders obvious all the asserted claims of the Poeze Patents.

(1) ’501 Patent, Claim 12

Lumidigm discloses all limitations of ’501 claim 12, as well as all limitations of claim 1 from which it depends. At a minimum, Lumidigm renders the claim obvious, alone and/or in combination with the general knowledge of a POSITA.

(a) ’501 Patent, Claim 1

Limitation 1/Preamble: Lumidigm discloses “[a] user-worn device configured to non-invasively measure a physiological parameter of a user.” Lumidigm discloses that its sensor can be incorporated in a variety of devices including a user-worn wristwatch. RX-0411 [Lumidigm] at 3:35-40, 10:42-49, Fig. 8B. Lumidigm explains that the “biometric reader 11 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin on the area of the wrist.” *Id.* at 11:61-64; *see also id.* at 11:36-59. Lumidigm’s sensor uses those signals to measure physiological parameters based on the “concentration of a substance in the individual’s tissue” and allows for the measurement of many kinds of physiological parameters, including but not limited to “oxygenation and/or hemoglobin levels in the blood.” *Id.* at 19:17-26; *see also id.* at 3:35-37, 4:7-29, 10:11-21, 19:16-28. A POSITA would have understood that Lumidigm’s wristwatch embodiment can include any of the functions for the sensor that Lumidigm describes, including the embodiments for measuring physiological parameters such as blood oxygenation. *Id.* at 3:35-37, 4:7-29, 10:11-21, 19:16-28; Warren Op. ¶¶ 187-88.

Lumidigm introduces the wristwatch embodiment after discussing numerous illustrative arrangements for the sensor's light sources, detectors, and sensor head, and confirms that "any of sensor geometries disclosed" can be used in the wristwatch embodiment. RX-0411 [Lumidigm] at 11:67-12:2; *see also id.* at 9:32-33. A POSITA would have understood that this would include any of the disclosed arrangements of LEDs, any of the disclosed arrangements of detectors, any of the disclosed arrangements for the sensor head including arrangements with openings over the detectors and a "compound curvature" between the sensor head and the tissue, and any of the disclosed components for processing and storing measurements. *Id.* at 11:36-12:2; Warren Op. ¶ 189; Rowe Tr. at 95:15-98:3.

Limitation [IA]: Lumidigm discloses "*at least three light emitting diodes (LEDs).*" Lumidigm teaches that its sensor can include any combination of light sources, including LEDs, in any variety of wavelengths. RX-0411 [Lumidigm] at 6:38-54. For example, each light source in a sensor can comprise "sets of LEDs, laser diodes VCSELs, or other solid-state optoelectronic device," and the light sources can have the same wavelength characteristics, differing wavelength characteristics, or some sources with the same wavelengths and others with different wavelengths. *Id.* at 6:43-53. Lumidigm also discloses that the sensor can include any number of light sources in any arrangement. The specification includes a series of illustrative examples in Figures 3 through 7B including examples with three or more LEDs, and confirms that other arrangements can be used. *Id.* at 9:23-33, Figs. 3-7B. For example, Figure 6 teaches that the sensor can have three light sources positioned relative to three detectors. *Id.* at 9:15-18, Fig. 6. Lumidigm also discloses that any of these sensor combinations can be used in the wristwatch embodiment. *Id.* at 11:64-12:2. A POSITA would have understood that Figures 3 through 7B are illustrative, that

piping through the protrusion.” RX-0411 [Lumidigm] at 7:12-14, 7:22-33, 9:21-25. A POSITA would have also understood that the use of opaque lateral surfaces as disclosed in Lumidigm allows light to pass through to the photodiodes while reducing light piping through the protrusion and other forms of optical noise. Warren Op. ¶ 218.

Limitation [1E]: Lumidigm discloses “*one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.*” Lumidigm discloses that its portable electronic devices, including the user-worn wristwatch implementation, include a “processor [that] is configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor.” RX-0411 [Lumidigm] at 3:21-31, 3:35-41, 4:7-29. This includes managing signals associated with physiological parameters including to measure oxygenation or hemoglobin levels. *Id.* at 4:20-29, 9:58-62, 19:16-26. Lumidigm repeatedly refers to the processors in its devices and confirms that the processors can “collect[] and digitize[] the spectral information.” *Id.* at 11:36-39, 11:64-65. Figure 9 provides an example of the processors in its devices, including hardware, software, memory, a communication system, and confirms that these elements can be implemented in a “separated or more integrated manner.” *Id.* at 12:56-13:4, 13:15-19.

A POSITA would have understood that the devices Lumidigm discloses would include one or more processors configured to use signals to calculate measurement of physiological parameters and that the processors could be implemented in a separate reader or integrated onto the same device. Warren Op. ¶¶ 221-22; Rowe Tr. at 101:18-102:11.

(b) **’501 Patent, Claim 12**

Lumidigm discloses “[t]he user-worn device of claim 1” for the reasons stated above for claim 1. Lumidigm further discloses “*wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a*

concave shape.” Lumidigm discloses a protrusion with a convex surface for the reasons stated above for ’501 claim 1, limitation [1C]. A POSITA would have understood that, when the sensor head has a “compound curvature on the optical surface” (i.e., the surface directly in contact with tissue), it has a convex protrusion. *See, e.g.*, RX-0411 [Lumidigm] at 7:58-63. A POSITA would have further recognized that, if the sensor head has a convex protrusion, the outermost surface of this protrusion will conform the user’s tissue into a concave shape when it contacts the user’s tissue. Warren Op. ¶ 260; Rowe Tr. at 134:1-7. A POSITA would have also understood that a convex protrusion would make the device more comfortable to wear, exhibit better contact with tissue, reduce slipping, create good coupling, and create optimal contact. Warren Op. ¶ 261.

(2) **’502 Patent, Claim 22**

Lumidigm discloses all limitations of ’502 claim 22, as well as all limitations of ’502 claims 19, 20, and 21 from which it depends. At a minimum, Lumidigm renders the claim obvious, alone and/or in combination with the general knowledge of a POSITA.

(a) **’502 Patent, Claim 19**

Limitation 19/Preamble: Lumidigm discloses a “*user-worn device configured to non-invasively measure*” a physiological parameter for the same reasons discussed above for ’501 claim 1, preamble. *See also* Warren Op. ¶¶ 681-83.

Lumidigm further discloses that its user-worn device “*measure[s] on oxygen saturation of the user.*” Lumidigm explains that its devices can be used to perform a variety of functions including “liveness” assessment and traditional “spectrometer” functions including measuring “physiological states” such as the concentration of alcohol, bilirubin, or hemoglobin and including a “hemoglobin monitor function.” RX-0411 [Lumidigm] at Abstract, 3:9-31, 3:40-47, 4:20-29, 19:16-19. Lumidigm explains that this functionality of its sensor monitors “spectroscopic changes [that] are correlated with oxygenation and/or hemoglobin levels in the blood.” *Id.* at 19:24-26;

a separate component, as in transmissive sensors) and that they would be configured to receive light attenuated by the tissue of the user. Warren Op. ¶ 699.

Limitation [19C]: Lumidigm discloses “*a protrusion comprising a convex surface*” for the same reasons discussed above for ’501 claim 1, limitation [1C]. *See also* Warren Op. ¶ 701.

Lumidigm discloses “*separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes*” for the reasons discussed above for ’501 claim 1, limitations [1C, 1D]. *See also* Warren Op. ¶¶ 702-03.

Lumidigm discloses “*the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue.*” Lumidigm expressly confirms that the openings or recesses over the photodiodes are made from “optically opaque material 37 that makes up the body of the sensor head 32,” that this configuration “minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue,” and that “[o]ther equivalent means of optical blocking can be readily established by one of ordinary skill in the art.” RX-0411 [Lumidigm] at 8:2-10; *see also* Warren Op. ¶¶ 704-06. Lumidigm further explains that the sensor can have a “reflectance” geometry” so that “when the tissue is illuminated by a particular light source 41, the resulting signal detected by the detector 36 contains information about the tissue optical properties along a path between the source 41 and detector 36.” RX-0411 [Lumidigm] at 7:12-14, 25-28; *see also id.* at 9:21-25, Figs. 2, 6.

A POSITA would have understood that non-invasive monitoring devices should have openings associated with photodiodes, and multiple openings when there are multiple photodiodes, so that reflected or transmitted light would reach the photodiodes. Warren Op. ¶ 707. A POSITA would have also understood that Lumidigm’s use of opaque lateral surfaces has the benefit of

allowing light to pass through to the photodiodes while reducing the amount of light reaching the photodiodes without being attenuated by the tissue. *Id.*

Limitation [19D]: Lumidigm discloses “*optically transparent material within each of the openings.*” Lumidigm explains that the protrusion can include “an optical relay (not shown) between the sensor surface 39 and the skin 40” that “transfers light . . . to the detector(s),” and that this can include “fiber optic face plates,” “individual optical fibers,” and “fiber bundles.” RX-0411 [Lumidigm] at 8:19-23, 8:24-26 (examples). A POSITA would have understood that fiber optic face plates, individual optical fibers, and fiber bundles were well known in the art, typically made of glass, and could be placed within or arranged over the openings. Rowe Tr. at 77:10-78:2, 81:14-21; Warren Op. ¶¶ 709-11. A POSITA would have recognized that an obvious way to implement fiber bundles would be to run a bundle through each of the individual openings; that the fiber bundles would pick up light reflected from the tissue and deliver it to photodiodes; that they would act as conduits to relay light from the tissue to the photodiodes such as, for example, taught in McCarthy 1992 (RX-0489); that they would permit the effective transfer of light even in small tissue cavities while maintaining signal quality; and that each bundle would be placed within and extend across a different opening. Warren Op. ¶ 710.

A POSITA would have recognized, and Lumidigm confirms, that a well-known way to implement the fiber optic face plate would be to place it “between the sensor surface 29 and the skin” to cover individual openings. RX-0411 [Lumidigm] at 8:19-20. A POSITA would have recognized that a fiber optic face plate would be beneficial because it would permit light to travel from the tissue to the photodiodes but avoid photons coming from outside the tissue rather than from the tissue; that it also could protect the photodiodes from damage or interference caused by

contaminants; and that it could be implemented by using a separate plate for each opening. *See id.* at 8:2-22; Warren Op. ¶ 711.

A POSITA would have understood that non-invasive, optical sensing devices should have optically transparent material extending through the protrusion associated with each photodiode and that the benefits would include providing a pathway for attenuated light to pass through to the photodiode while protecting the photodiode from damage or interference caused by contaminants from a user. Warren Op. ¶ 712.

Limitation [19E]: Lumidigm discloses “*one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals*” for the same reasons discussed above for 501 claim 1, limitation [1E]. *See also* Warren Op. ¶¶ 714-20. Lumidigm discloses both calculating and outputting measurements based on signals from the photodiodes. RX-0411 [Lumidigm] at 3:21-25, 35-38, 41, 4:7-29, 9:58-60, 19:17-26, 11:36-39, 11:64-65, 12:62-13:4, 13:15-19, Fig. 9; *see also* Warren Op. ¶¶ 714-16. A POSITA would have understood that the devices Lumidigm discloses would include one or more processors configured to use signals to output measurements of physiological parameters and that the processors could be implemented in a separate reader or integrated onto the same device. *See* Warren Op. ¶¶ 715-16; Rowe Tr. at 101:18-102:11.

Lumidigm also discloses that its processors can output a measurement “*indicative of the oxygen saturation of the user*” for the same reasons discussed above for 502 claim 19, preamble. A POSITA would have recognized that it is the processors in the device that output the measurement associated with this function. *See* Warren Op. ¶¶ 717-20.

(b) ’502 Patent, Claim 20

Lumidigm discloses “[t]he user-worn device of claim 19,” for the reasons discussed above for claim 19.

Lumidigm discloses “*further comprising a thermistor.*” Lumidigm discloses that its sensor may include “additional preprocessing steps” including “performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature” and other factors. RX-0411 [Lumidigm] at 14:21-28. Lumidigm also correctly comments that “[t]hese and other techniques are well-known in the art.” *Id.* at 14:29. A POSITA would have recognized that a thermistor was one of the “well-known” techniques in the art to perform “explicit correction” for the “environmental influence[] of temperature,” and that it would have been obvious to include a thermistor in Lumidigm’s device to take temperature readings so the device could use those temperature signals to adjust its operation. *See* Warren Op. ¶¶ 253-54, 723.

(c) **’502 Patent Claim 21**

Lumidigm discloses “*[t]he user-worn device of claim 20,*” for the reasons discussed above for claim 20.

Lumidigm discloses “*wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.*” As discussed above for claim 20, Lumidigm discloses a thermistor for taking temperature readings and adjusting operations based on those readings and confirms that performing “explicit corrections” for “environmental influences of temperature” is “well known in the art.” RX-0411 [Lumidigm] at 14:21-29; Warren Op. ¶¶ 256-57, 725. Moreover, as discussed above in connection with ’501 claim 1, limitation [1E], Lumidigm repeatedly refers to its sensor’s processors throughout the specification. *See, e.g.,* RX-0411 [Lumidigm] at 12:63-13:4. A POSITA would have understood that adjusting operations based on temperature requires, in addition to the thermistor, one or more processors and additional preprocessing steps to receive the temperature signal from the thermistor and to adjust operation of the sensor responsive to the temperature signal. *See* Warren Op. ¶¶ 256-57, 725.

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Inv. No. 337-TA-1276

**ORDER NO. 33: INITIAL DETERMINATION GRANTING COMPLAINANTS'
SECOND UNOPPOSED MOTION FOR PARTIAL TERMINATION
BY WITHDRAWAL OF CERTAIN CLAIMS**

(May 20, 2022)

On May 17, 2022, Complainants Masimo Corporation and Cercacor Laboratories, Inc. filed a motion (1276-043) to withdraw its allegations of infringement with respect to claims 1, 3, 6, 8, 9, 13-15, 17, 18, and 21 of U.S. Patent No. 10,912,501 (“the ’501 patent”), claims 19, 21, 24, 29, and 30 of U.S. Patent No. 10,912,502 (“the ’502 patent”), claims 1, 2, 5, 8, 11, 20, 21, 23, and 29 of U.S. Patent No. 10,945,648 (“the ’648 patent”), and claim 2 of U.S. Patent No. 10,687,745 (“the ’745 patent”). Respondent Apple Inc. does not oppose Complainants’ withdrawal of these allegations. *See* Motion at 5.


Commission Rule 210.21(a)(1) provides that “[a]ny party may move at any time prior to the issuance of an initial determination on violation of section 337 of the Tariff Act of 1930 to terminate an investigation in whole or in part as to any or all respondents, on the basis of withdrawal of the complaint or certain allegations contained therein” 19 C.F.R. § 210.21(a)(1). The Commission has held that “in the absence of extraordinary circumstances, termination of an investigation will be readily granted to a complainant during the prehearing stage of an investigation.” *Certain Ultrafiltration Membrane Systems, & Components Thereof*

Including Ultrafiltration Membranes, Inv. No. 337-TA-107, Comm'n Action & Order at 2 (Mar. 11, 1982).

In compliance with Commission Rules, the motion states that other than discovery stipulations, “there are no agreements, written or oral, express or implied between the parties concerning the subject matter of the investigation.” Motion at 4. Complainants submit that the narrowing of the asserted claims will simplify the issues in the investigation and conserve judicial resources. *Id.* at 3. The undersigned finds that the motion complies with Commission Rule 210.21(a)(1), and there are no extraordinary circumstances preventing the withdrawal of the identified allegations.

Accordingly, the motion (1276-043) is hereby GRANTED, and it is the undersigned’s initial determination that the identified allegations of infringement shall be terminated from the investigation.¹ Pursuant to Commission Rule 210.42(h), this initial determination shall become the determination of the Commission unless a party files a petition for review of the initial determination pursuant to Commission Rule 210.43(a), or the Commission, pursuant to Commission Rule 210.44, orders, on its own motion, a review of the initial determination or certain issues contained herein. 19 C.F.R. § 210.42(d).

SO ORDERED.



Monica Bhattacharyya
Administrative Law Judge

¹ Complainants previously withdrew certain asserted claims pursuant to Order No. 35 (Mar. 23, 2022), *not reviewed by* Comm’n Notice, EDIS Doc. ID 768023 (Apr. 12, 2022). The asserted claims remaining in the investigation are claim 12 of the ’501 patent, claims 22 and 28 of the ’502 patent, claims 12, 24, and 30 of the ’648 patent, claims 9 and 27 (and claim 18 for domestic industry) of the ’745 patent, and claim 9 of U.S. Patent No. 7,761,127 (“the ’127 patent”). *See* Motion at 3-4.

Certain Light-Based Physiological Measurement Devices and Components Thereof; Inv. 337-1276 Violation
No. 337-TA-1276 (Violation)

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached document has been served via EDIS upon the Commission OUII Investigative Attorney and the following parties as indicated, upon the date listed below.

Document	Security	Document Type	Official Rec'd Date	Title
771234	Public	ID/RD - Other Than Final on Violation	05/20/2022 12:05 PM	Initial Determination Granting Complainants' Second Unopposed Motion for Partial Termination by W...

Service Date: May 20, 2022

/s/

Lisa R. Barton
U.S. International Trade Commission
500 E Street, S.W.
Suite 112
Washington, D.C. 20436

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

COMPLAINANTS' INITIAL POST-HEARING BRIEF

[REDACTED]

CDX-0015C.014 (summarizing CX-0629C; CX-0634C; CX-0635C; CX-0636C; CX-0640C; CX-0641C; CX-0644C; CX-0646C; CX-0647C; CX-0649C).

Masimo addresses the significance of its domestic expenditures regarding the rainbow® Sensors in the subsequent section within the heading for labor or capital.

B. Significant Employment of Labor or Capital

1. Masimo Watch

Masimo has employed [REDACTED] in eligible domestic labor or capital specifically for the Masimo Watch, [REDACTED] in labor or capital for R&D on [REDACTED]

[REDACTED]

[REDACTED]

Masimo's domestic employment of labor or capital for the Masimo Watch between 2019 Q3 and 2021 Q1 have included (*see* CDX-0006C.004):

- [REDACTED]
[REDACTED] (CX-0629C at "[REDACTED]
[REDACTED]" tab; Tr. (Young) at 489:2-21);
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (Tr. (Young) at 489; CX-0635C at R&D Summary tab; CDX-0006C.008 (summarizing CX-0635C at [REDACTED] tabs));
- [REDACTED]
[REDACTED] (Tr. (Young) at

[REDACTED]
[REDACTED]
490:19-492:13; CX-0635C at [REDACTED]; CDX-0006C.010 (excerpting CX-0635C; CX-0611C; CX-0835C at 41);

- [REDACTED] (Tr. (Young) at 492:11:15; CX-0635C at [REDACTED]);
- [REDACTED]
[REDACTED]
[REDACTED] (Tr. (Young) at 492:16-493:7; CX-0635C at [REDACTED]
[REDACTED]);
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (Tr. (Young) at 493:8-494:17; CX-0624C [REDACTED]
- [REDACTED] (Tr. (Young) at 494:18-22; CX-0623C at “Summary” tab);
- [REDACTED]
(Tr. (Young) at 494:23-495:2; CX-0646C at “Summary” tab);
- [REDACTED] (Tr. (Young) at 495:3-10; CX-0632C at “Summary” tab);
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (CX-0618C at 4 and 5), and [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] (CX-0620C at 14) (Tr. (Young) at 495:11-496:19).

Masimo's domestic expenditures in the categories immediately above for the Masimo Watch total [REDACTED]

Moreover, the development of the Masimo Watch relied on [REDACTED]
[REDACTED]
Tr. (McGavock) at 560:6-561:1. Masimo has estimated that [REDACTED] in total U.S.-based R&D in that timeframe has been devoted to wrist-worn technology—ranging between [REDACTED] annually. CX-0640C at “Summary” tab; Tr. (Young) at 497:1-20.

Even pursuant to Thomas' opinion excluding Masimo's wrist-worn expenditures, post-complaint expenditures, and expenditures from before 2019, that would still leave [REDACTED] in labor or capital that Masimo has spent on qualified domestic activities for the Masimo Watch. (CDX-0015C.010 (summarizing CX-0618C, CX-0620C, CX-0623C, CX-0624C, CX-0629C, CX-0632C, CX-0634C, CX-0635C, CX-0636C, CX-0646C, CX-0647C); Tr. (McGavock) at 541:22-543:2.

Masimo [REDACTED]
[REDACTED] (see CDX-0006C.0030-31; Tr. (Young) at 500:23-502:1):

- [REDACTED] (CX-0635C at R&D Summary tab);
- [REDACTED] (CX-0635C at “R&D Summary” tab, “Capital items” row);

- [REDACTED]
[REDACTED]
- | [REDACTED]
[REDACTED]
- | [REDACTED]
[REDACTED]
- | [REDACTED]
- | [REDACTED]
[REDACTED]
- | [REDACTED]
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- | [REDACTED]
[REDACTED]
- | [REDACTED]
[REDACTED]
- | [REDACTED]
[REDACTED]

Masimo's projected domestic expenditures in the categories immediately above for the Masimo Watch total [REDACTED] in addition to the pre-Complaint expenditures.

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

**In the Matter of
CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S POST-HEARING BRIEF

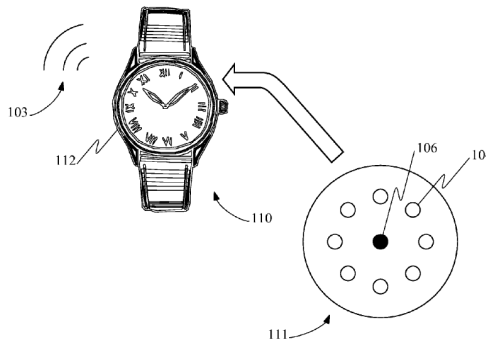
(2) '501 Patent, Claim 12

Lumidigm discloses all limitations of '501 claim 12 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1207:1-1215:10.

(a) '501 Patent, Claim 1

Limitation [1Preamble]: Lumidigm discloses “[a] user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising.”

Lumidigm discloses that its sensor can be incorporated into a variety of devices including a user-worn wristwatch, as shown in Figure 8B:

**FIG. 8B**

RX-0411 at 11:60-12:2, Fig. 8B; Tr. [Warren] 1207:23-1208:13; RDX-8.23 (summarizing RX-0411).

Lumidigm explains that, in this embodiment, the “biometric reader 11 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin on the area of the wrist.” RX-0411 at 11:61-64. Lumidigm’s sensor uses those signals to measure physiological parameters, based on the “concentration of a substance in the individual’s tissue,” including “oxygenation and/or hemoglobin levels in the blood.” *Id.* at 19:16-28, *see also* 11:61-64; Tr. [Warren] 1208:1-13, 1214:12-1215:4.

Lumidigm introduces its wristwatch embodiment after discussing numerous illustrative arrangements for the sensor’s light sources, detectors, and sensor head, and confirms that “any of

the sensor geometries previously disclosed or other equivalent configurations” can be used in the wristwatch embodiment. RX-0411 at 11:60-12:2. A POSITA²² would have understood that this would include any of the disclosed arrangements of LEDs and photodiodes, any of the disclosed geometries for the sensor head including a “compound curvature,” and any equivalent configurations. Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4.

Limitation [1A]: Lumidigm discloses “*at least three light emitting diodes (LEDs).*”

The concept of using multiple LEDs in a sensor has been “known for many decades.” Tr. [Warren] 1208:14-23, *see also* 1189:25-1191:22, 1195:6-12. Lumidigm teaches that its sensor can include any type of light sources, including LEDs, in any variety of wavelengths. RX-0411 at 6:38-53. For example, each light source in a sensor can comprise “sets of LEDs, laser diodes VCSELs, or other solid-state optoelectronic device,” and the light sources can have the same wavelength characteristics, differing wavelength characteristics, or some sources with the same wavelengths and others with different wavelengths. *Id.* at 6:43-53; Tr. [Warren] 1208:14-23. Lumidigm also discloses that the sensor can include any number of light sources, in any arrangement.

Lumidigm includes a series of illustrative examples in Figures 2 through 7B, including examples with three or more LEDs, and confirms that “other arrangements” also can be used. RX-0411 at 9:26-34, Figs. 2-7B. For example, Figure 6 teaches that the sensor can have *three LEDs* positioned relative to three photodiodes:

²² Professor Warren confirmed that he applied the parties’ agreed definition of a person of ordinary skill in the art in evaluating anticipation and obviousness. Tr. [Warren] 1207:1-22. All references to a “POSITA” in this brief, for purposes of the Poeze Patents, are from the perspective of a POSITA with this skill level, as of the priority date of the Poeze Patents.

The concept of including a processor to receive signals from photodiodes, calculate measurements, and “manage the overall set of events” is another “well-known idea.” Tr. [Warren] 1213:4-1214:1. Lumidigm discloses that its portable devices, including the user-worn wristwatch, include a “processor [that] is configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor.” RX-0411 at 3:28-31. Lumidigm repeatedly refers to the processors in its devices, and confirms that “[o]nce the light passing through the tissue is detected, the signals can be digitized and recorded by standard techniques,” and the “recorded data can then be processed” into spectral data “as is known to one of ordinary skill in the art.” *Id.* at 9:58-62. This would include receiving and processing signals from the photodiodes and calculating physiological measurements. Tr. [Warren] 1213:4-1214:1; RX-0411 at 19:16-28 (confirming that system “quantif[ies] oxygenation levels”).

Figure 9 provides an example of a “computational device” for “management of the functionality discussed herein” including “processor 332” and “processing acceleration unit 346”:

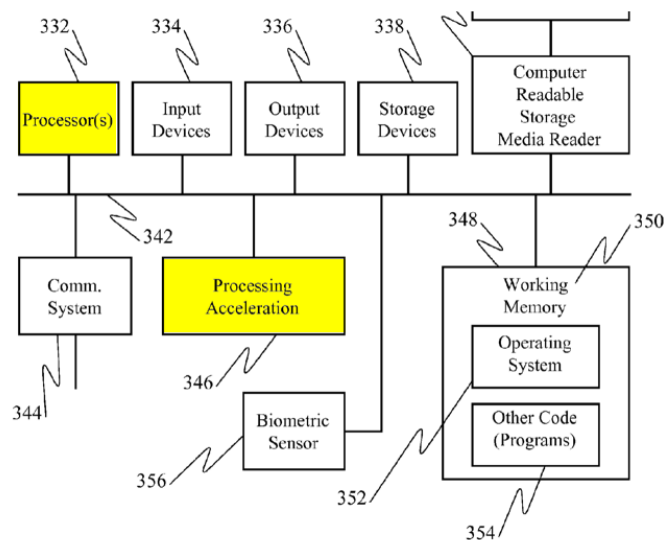


FIG. 9

RX-0411 at Fig. 9, 12:56-67; Tr. [Warren] 1213:4-1214:1; RDX-8.30 (summarizing RX-0411).

Lumidigm further confirms that the components in Figure 9 can be implemented in a “separated

or more integrated manner.” RX-0411 at 12:61-63. A POSITA would have understood that the processors could be implemented in a separate reader or integrated onto the same device as the sensor. Tr. [Warren] 1213:4-1214:1.

(b) '501 Patent, Claim 12

Lumidigm discloses “[t]he user-worn device of claim 1” for the reasons stated above for claim 1.

Lumidigm further discloses “*wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape*.” Lumidigm discloses a “protrusion with a convex surface” for the reasons stated above for '501 limitation [1C]. A POSITA would have recognized that, if a sensor has a protrusion with a convex surface, and that protrusion is positioned next to tissue, “any pressure at all will conform the tissue into a concave shape.” Tr. [Warren] 1214:2-11. Dr. Madisetti confirmed the same understanding. Tr. [Madisetti] 686:1-18.

(3) '502 Patent, Claim 22

Lumidigm discloses all limitations of '502 claim 22 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1215:11-1224:2.

(a) '502 Patent, Claim 19

Limitation [19Preamble]: Lumidigm discloses “[a] *user-worn device configured to non-invasively measure*” a physiological parameter for the reasons discussed above for '501 claim 1, preamble.

Lumidigm further discloses that its user-worn device “*measure[s] an oxygen saturation of a user*.” Lumidigm explains that its devices can be used to perform a variety of functions including measuring the “physiological state of an individual” using “a hemoglobin monitor.” RX-

0411 at 19:16-19. Lumidigm further explains that this functionality detects “spectroscopic changes [that] are correlated with oxygenation and/or hemoglobin levels in the blood” and provides “the ability to quantify oxygenation levels.” *Id.* at 19:22-28; RDX-8.35 (summarizing RX-0411).

A POSITA would have recognized from these disclosures that Lumidigm’s devices are configured to quantify oxygenation levels. Tr. [Warren] 1215:18-1216:9. Moreover, a POSITA “would not have needed any additional information to make [pulse oximetry functionality] work” in Lumidigm’s watch embodiment because this functionality was well understood at the time. *Id.* at 1216:10-25. In fact, Professor Warren and his students were able to build sensors and “work[] with them on their wrists” years earlier. *Id.* Although Apple had significant challenges to overcome in implementing pulse oximetry on Apple Watch, given the limited space and other competing features in Apple Watch, the simple light management problems addressed in the Poeze Patents had already been solved. DocID 773735 (substituting Warren Op. ¶ 244 for Tr. [Warren] 1217:11-21); Tr. [Warren] 1243:5-16.

Limitation [19A]: Lumidigm discloses “*a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs).*”

Lumidigm discloses that its sensor can include any number and arrangement of LEDs, including in its wristwatch embodiment, for the reasons discussed above for ’501 claim 1, limitation [1A]. *E.g.*, RX-0411 at 6:38-53, 11:60-12:2, Fig. 6. Lumidigm further explains that the “light sources” can include “sets of LEDs.” *Id.* at 6:48-53. A POSITA would have understood a “set of LEDs” as a “grouping” of LEDs, each including “for example, three LED dies.” Tr. [Warren] 1190:25-1191:6, 1205:1-11.

The concept of including four or more emitters in an optical sensor, each comprising a set of LEDs, has been known for at least thirty years. Tr. [Warren] 1191:7-22, 1195:10-12. Lumidigm's illustrative examples including multiple examples with four or more sets of LEDs, including Figures 3, 5, 7A and 7B:

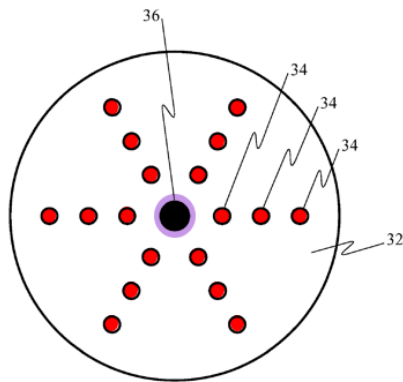


FIG. 3

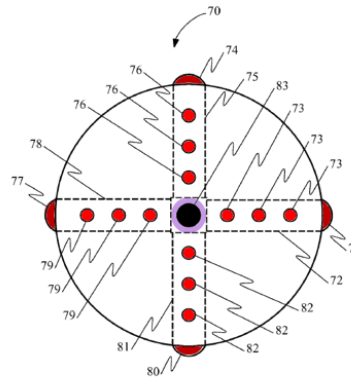


FIG. 5

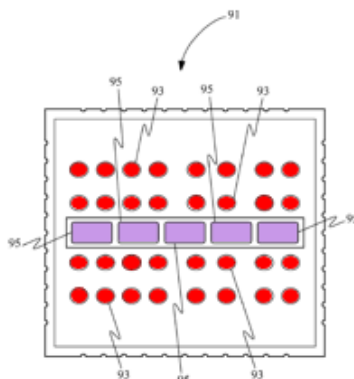


FIG. 7A

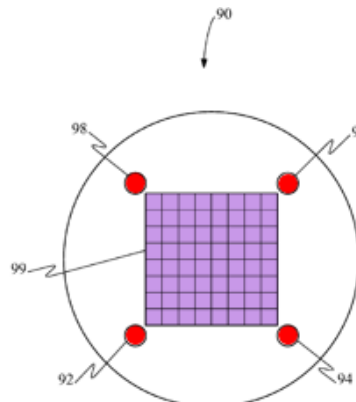


FIG. 7B

RX-0411 at Figs. 3, 5, and 7A-7B, 9:30-33; Tr. [Warren] 1220:12-1221:8.

A POSITA would have understood that the light sources disclosed in these examples would include at least four emitters, each with a set of three LEDs. Tr. [Warren] 1220:12-1221:8; RX-0411 at 6:38-53, Figs. 3, 5, and 7A-7B; RDX-8.36 (summarizing RX-0411). For example, Figure 3 would include 6 emitters, each with three radial LEDs (where the light sources are *single* LEDs) or 18 light sources, each with three LEDs in a set (where the light sources are *sets* of LEDs). See

discussed above for '501 claim 1, limitation [1B]. For example, Lumidigm explains that the light detectors are “disposed relative to the light sources to detect light from the light sources that has propagated through the tissue.” RX-0411 at 3:25-28; 7:26-29. A POSITA would have understood that the photodiodes would be configured to receive light attenuated by the tissue of the user. Tr. [Warren] 1209:19-1210:11.

Limitation [19C]: Lumidigm discloses “*a protrusion comprising a convex surface*” for the reasons discussed above for '501 claim 1, limitation [1C].

Lumidigm discloses “*separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes*” for the reasons discussed above for '501 claim 1, limitations [1D], [1E].

Lumidigm discloses “*the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue*” for the reasons discussed above for '501 claim 1, limitation [1E]. For example, Lumidigm expressly confirms that the openings over the photodiodes are made from “optically opaque material 37,” that this configuration “minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue,” and that “[o]ther equivalent means of optical blocking can be readily established by one of ordinary skill in the art”:

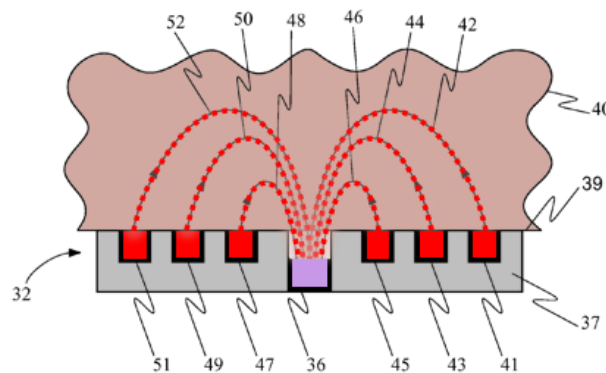


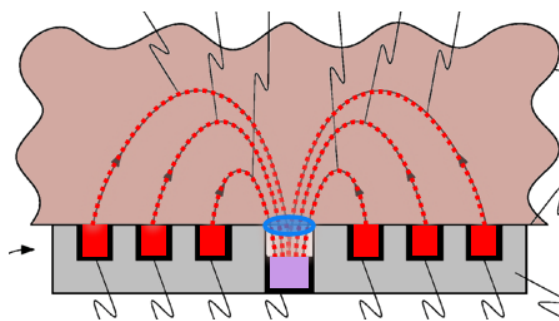
FIG. 2

RX-0411 at Fig. 2, 8:1-11; Tr. [Warren] 1212:11-1213:3. RDX-8.29 (summarizing RX-0411). Lumidigm further explains that the sensor can have a “reflectance geometry” so that “when the tissue is illuminated by a particular light source 41, the resulting signal detected by the detector 36 contains information about the tissue optical properties along a path between the source 41 and detector 36.” RX-0411 at 7:12-14, 7:26-29.

A POSITA would have also understood that Lumidigm’s use of openings made from opaque material has the benefit of allowing light to pass through to the photodiodes while reducing light piping, or the amount of light reaching the photodiodes without being attenuated by the tissue. Tr. [Warren] 1212:11-1213:3.

Limitation [19D]: Lumidigm discloses “*optically transparent material within each of the openings.*”

The use of windows or other optically transparent materials, within or across openings over photodiodes, was also “well-known.” Tr. [Warren] 1221:16-12:22-9, 1193:24-1194:14. Consistent with this well-known idea, Lumidigm explains that its sensor can incorporate “an optical relay (not shown) between the sensor surface 39 and the skin 40” that “transfers the light . . . from the skin back to the detector(s),” and that this optical relay can include “fiber optic face plates,” “individual optical fibers,” and “fiber bundles.” RX-0411 at 8:19-26. Professor Warren illustrates this optical relay in blue in Figure 2:



RX-0411 at Fig. 2; Tr. [Warren] 1221:16-1222:16; RDX-8.38 (summarizing RX-0411).

A POSITA would have understood that fiber optic face plates, individual optical fibers, and fiber bundles were well-known in the art, typically made of glass or plastic cladding, and could be placed within or arranged over the openings. Tr. [Warren] 1221:16-1222:25. A POSITA would have recognized, and Lumidigm confirms, that a well-known way to implement a fiber optic face plate would be to place it “between the sensor surface 39 and the skin” to cover individual openings. RX-0411 at 8:19-21; Tr. [Warren] 1221:16-1222:16. A POSITA would have further recognized that a fiber optic face plate could be implemented as a “single faceplate for multiple openings,” or as “an individual faceplate for each of the individual openings.” Tr. [Warren] 1221:16-1222:9. A POSITA would have recognized that a fiber optic face plate would be beneficial because it would “transfer light” from the tissue to the photodiodes and “protect the detector from dust and debris and dirt.” *Id.* at 1193:24-1194:7, 1221:16-1222:16. A “fiber bundle” would similarly “direct light from a portion of tissue straight to the detector as a means to optimize the detection process.” *Id.* at 1222:10-16.

A POSITA would have thus understood that non-invasive, optical sensing devices should have optically transparent material extending across the openings over the photodiodes and that the benefits would include providing a pathway for attenuated light to pass through to the photodiode while protecting the photodiode from damage or interference caused by contaminants from a user. *Id.* at 1193:24-1194:7, 1221:16-1222:25.

Limitation [19E]: Lumidigm discloses “*one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals*” for the reasons discussed above for 501 claim 1, limitation [1E]. For example, Lumidigm discloses both calculating and outputting measurements based on

signals from the photodiodes. RX-0411 at 3:28-31, 9:58-59, 12:56-13:14, Fig. 9; Tr. [Warren] 1213:4-1214:1. A POSITA would have understood that Lumidigm’s “computational devices” include one or more processors configured to use signals to output measurements of physiological parameters and that the processors could be implemented in a separate reader or integrated onto the same device. Tr. [Warren] 1213:4-1214:1.

Lumidigm also discloses that its processors can output a measurement “*indicative of the oxygen saturation of the user*” for the reasons discussed above for ’502 claim 19, preamble. A POSITA would have recognized that it is the processors in the device that output the measurements associated with Lumidigm’s blood oxygen function. Tr. [Warren] 1215:18-1216:25; RX-0411 at 19:16-19, 19:22-28, Fig. 9; RDX-8.35 (summarizing RX-0411).

(b) ’502 Patent, Claim 20

Lumidigm discloses “[t]he *user-worn device* of claim 19,” for the reasons discussed above for ’502 claim 19.

Lumidigm also discloses “*further comprising a thermistor.*” This limitation relates to the “well-known notion” that “LEDs will change their behavior depending on temperature,” and that if a processor “can receive a temperature signal, in this case from a thermistor, it can adjust the operation of the user worn device.” Tr. [Warren] 1223:1-20. Consistent with this notion, Lumidigm discloses that its sensor may include “additional preprocessing steps” including “performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature” and other factors. RX-0411 at 14:21-28, Fig. 9; RDX-8.39 (summarizing RX-0411). Lumidigm also correctly comments that “[t]hese and other techniques are well-known in the art.” *Id.* at 14:29.

A POSITA would have recognized that a thermistor was one of the “well-known” techniques in the art to perform “explicit corrections” for the “environmental influence[] of temperature,” and it would have been obvious to include a thermistor in Lumidigm’s device to take temperature readings so the processor could use that temperature signal to adjust operations. Tr. [Warren] 1223:1-20.

(c) ’502 Patent Claim 21

Lumidigm discloses “[t]he *user-worn device* of claim 20,” for the reasons discussed above for ’502 claim 20.

Lumidigm discloses “*wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.*” As discussed above for ’502 claim 20, Lumidigm discloses “performing explicit corrections” to account for “environmental influences of temperature” and confirms this is “well known in the art.” RX-0411 at 14:21-29, Fig. 9; RDX-8.39 (summarizing RX-0411). Moreover, as discussed above in connection with ’501 claim 1, limitation [1E], Lumidigm repeatedly refers to its sensor’s processors throughout the specification. *E.g.*, RX-0411 at 12:61-67, Fig. 9. A POSITA would have understood that adjusting operations based on temperature requires, in addition to the thermistor, one or more processors to receive the temperature signal from the thermistor and to adjust operation of the sensor responsive to the temperature signal. Tr. [Warren] 1223:1-20.

(d) ’502 Patent, Claim 22

Lumidigm discloses “[t]he *user-worn device* of claim 21,” for the reasons discussed above for ’502 claim 21.

Lumidigm also discloses “*wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs,*” for the reasons discussed above for ’502 limitation [19A]. The illustrative examples discussed in connection with ’502 limitation [19A] include four emitters, each with a respective set of three LEDs. Tr. [Warren] 1220:13-1221:6.

(4) ’502 Patent, Claim 28

Lumidigm discloses all limitations of ’502 claim 28 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1224:3-1227:21.

Limitation [28Preamble]: Lumidigm discloses “[a] *user-worn device configured to noninvasively measure an oxygen saturation of a user, the user-worn device comprising*” for the reasons discussed above for ’502 claim 19, preamble.

Limitation [28A]-[28B]: Lumidigm discloses “*a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength*” and “*a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength.*”

As discussed above, the concept of including multiple emitters in an optical sensor, each comprising a set of LEDs, has been known for at least thirty years. Tr. [Warren] 1191:7-22, 1195:10-12. Each set of LEDs would include “for example, three LED dies,” and “multiple wavelengths would be present, for example, in a multi-chip LED package.” *Id.* at 1190:25-1191:6, 1205:1-11, 1224:23-1225:5.

Consistent with this “well-known idea,” (Tr. [Warren] 1224:23-1225:5), Lumidigm discloses that its sensor can include any number and arrangement of LEDs, including sets of LEDs, and including in its wristwatch embodiment, for the reasons discussed above for ’501 claim 1, limitation [1A], ’502 claim 19, limitation [19A], and ’502 claim 22. Lumidigm further explains that the light sources “can include some sources that have the same wavelengths as others and some sources that are different” and can include “sets of LEDs . . . with differing wavelength characteristics.” RX-0411 at 6:38-53.

A POSITA reading Lumidigm would have understood that its sensor could include sets of LEDs; that those sets of LEDs could include LEDs of the same variety of differing wavelengths; and that a multi-chip LED package (a “source” in Lumidigm), commonly used at the time, could encapsulate a plurality of LED dies at multiple different wavelengths. Tr. [Warren] 1190:25-1191:6, 1224:9-1225:12.

Lumidigm provides multiple specific examples including the recited “first set” and “second set” of LEDs, which are “spaced apart” from each other, and which include LEDs configured to emit at a “first wavelength” and a “second wavelength,” including the examples in Figures 3, 5, 6, 7A, and 7B:

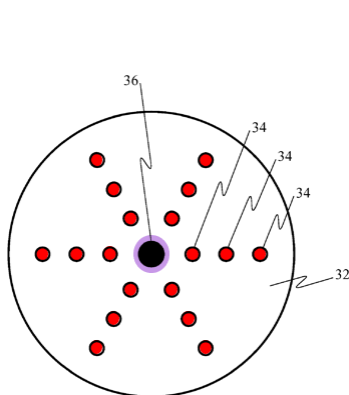


FIG. 3

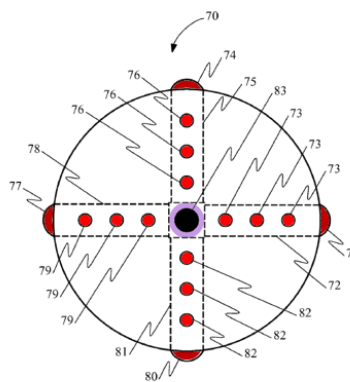


FIG. 5

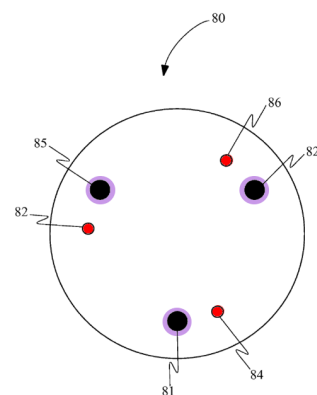


FIG. 6

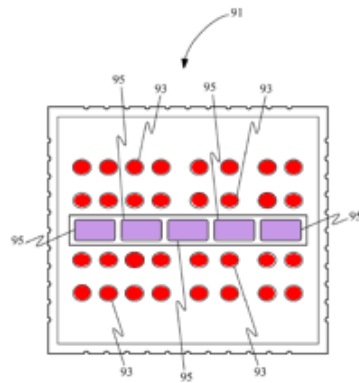


FIG. 7A

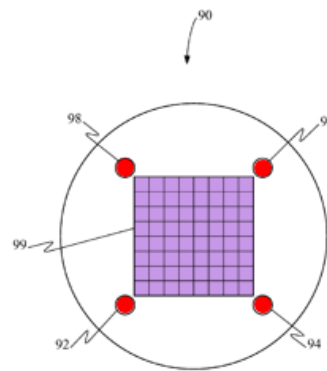


FIG. 7B

RX-0411 at Figs. 3, 5-6, and 7A-7B; Tr. [Warren] 1224:9-1225:12; RDX-8.42-RDX-8.43 (summarizing RX-0411). A POSITA would have understood, consistent with Lumidigm's disclosures, that each light source in these figures could comprise a set of LEDs, and that these sets of LEDs would be spaced apart from each other as shown in the figures. *Id.* at 6:38-53; Tr. [Warren] 1224:9-1225:12. A POSITA would have further understood that each set of LEDs would include LEDs configured to emit at a "first wavelength" and a "second wavelength," so that in each source location "multiple wavelengths would be present" (as in a multi-chip package). *Id.*

Lumidigm also incorporates by reference U.S. Patent Application Ser. No. 10/262,403 (RX-0411 at 1:40-44), which discloses in its Figure 6 multiple sets of LEDs, each with LEDs emitting at "first" and "second" wavelengths. RX-0460 ['403 Application] at Fig. 6, *see also* [0054]. A POSITA would recognize this as an example of the type of "sets of LEDs" that could readily be incorporated into Lumidigm's figures, particularly given that Lumidigm incorporates the application by reference and thus expressly suggests such a combination. Tr. [Warren] 1224:9-1225:12.

Limitation [28C]: Lumidigm discloses "*four photodiodes . . . configured to receive light after at least a portion of the light has been attenuated by the tissue of the user*" for the reasons discussed above for '502 claim 19, limitation [19B].

(5) '648 Patent, Claim 12

Lumidigm discloses all limitation of '648 claim 12 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1227:22-1228:10.

(a) '648 Claim 8

Limitation [8Preamble]: Lumidigm discloses “a *user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising*” for the reasons discussed above for '501 claim 1, preamble.

Limitation [8A]/[8B]: Lumidigm discloses “a *first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength*” and “a *second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength,*” for the reasons discussed above for '502 claim 28, limitations [28A] and [28B].

Limitation [8C]: Lumidigm discloses “*four photodiodes*” for the reasons discussed above for '502 claim 19, limitation [19B] and '502 claim 28, limitation [28C].

Limitation [8D]: Lumidigm discloses “a *protrusion comprising a convex surface*” for the reasons discussed above for '501 claim 1, limitation [1C].

Lumidigm also discloses in “*at least a portion of the protrusion comprising an opaque material*” for the reasons discussed above for '501 claim 1, limitation [1E], and '502 claims 19, limitation [19C], and claim 28, limitations [28F] and [28H]. Although this claim specifies that a portion of the protrusion comprises opaque material, rather than the surfaces of the openings or a wall, the same reasoning applies. Tr. [Warren] 1227:22-1228:2. Lumidigm explains that “the

body of the sensor head 32,” which includes the protrusion, is made from “optically opaque material 37” to provide “optical blocking” and minimize unwanted light. RX-0411 at 8:1-11.

Limitation [8E]: Lumidigm discloses “*a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes*” for the reasons discussed above for ’501 claim 1, limitation [1D], ’502 claim 19, limitation [19C], and ’502 claim 28, limitation [28F]. The same reasoning applies. Tr. [Warren] 1227:22-1228:2.

Limitation [8F]: Lumidigm discloses “*a separate optically transparent window extending across each of the openings*” for the reasons discussed above for ’502 claim 19, limitation [19D] and ’502 claim 28, limitation [28G]. Although this claim specifies a “separate optically transparent window” across each opening, rather than transparent material or a transmissive window, the same reasoning applies. Tr. [Warren] 1227:22-1228:2. A POSITA would have recognized that the fiber optic face plates and fiber bundles referenced in Lumidigm and discussed in connection with above limitations are optically transparent windows and that each would extend across a different one of the openings. Tr. [Warren] 1221:16-1222:25.

Limitation [8G]: Lumidigm discloses “*one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user*” for the reasons discussed above for ’502 claim 19, Limitation [19E].

Limitation [8H]: Lumidigm discloses “*a housing*.” For example, Lumidigm discloses that, for its wristwatch embodiment, “the biometric reader 111 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin in the area of the wrist.” RX-0411 at 11:60-64, Fig. 8B; Tr. [Warren] 1228:3-6; RDX-8.52 (summarizing RX-0411).

Limitation [8I]: Lumidigm discloses “*a strap configured to position the housing proximate tissue of the user when the device is worn*” for the reasons discussed above with respect to claim 28, limitation 28[M].

(b) '648 Claim 12

Lumidigm discloses “[t]he user-worn device of claim 8,” for the reasons discussed above for '648 claim 8.

Lumidigm discloses “*wherein the physiological parameter comprises oxygen or oxygen saturation*” for the reasons provided above with respect to claim '502 claim 19, preamble.

(6) '648 Patent, Claims 24 and 30

Lumidigm discloses all limitations '648 claims 24 and 30 and anticipates these claims or, at a minimum, renders them obvious. Tr. [Warren] 1228:11-1229:14.

(a) '648 Claim 20

Limitation [20Preamble]: Lumidigm discloses “[a] user-worn device configured to non-invasively determine measurements of a user’s tissue, the user-worn device comprising” for the reasons discussed above with respect to '501 claim 1, preamble.

Limitation [20A]: Lumidigm discloses “*a plurality of light emitting diodes (LEDs)*” including for the reasons discussed above for '501 claim 1, limitation [1A].

Limitation [20B]: Lumidigm discloses “*at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user*” for the reasons discussed above for '502 claim 19, limitation [19B] and '502 claim 28, limitation [28C]. Although this claim specifies that the four photodiodes are “arranged to capture light at different quadrants of tissue of a user,” rather than being arranged “in a quadrant configuration,” the same reasoning applies. Tr. [Warren] 1228:11-15.

Limitation [20C]: Lumidigm discloses “*a protrusion comprising a convex surface*” for the reasons discussed above for ’501 claim 1, limitation [1C], ’502 claim 19, limitation [19C], and ’502 claim 28, limitations [28E].

Limitation [20D]: Lumidigm discloses “*a plurality of through holes . . . arranged over a different one of the at least four photodiodes*” for the reasons discussed above for ’501 claim 1, limitation [1D], ’502 claim 19, limitation [19C] and ’502 claim 28, limitations [28F]. Although this claim refers to “through holes” rather than “openings,” the same reasoning applies. Tr. [Warren] 1211:10-1212:10, 1224:3-8, 1227:22-1228:2.

Lumidigm also discloses “*each through hole including a window*” for the reasons discussed above for ’502 claim 19, limitation [19D] and ’502 claim 28, limitation [28G].

Limitation [20E]: Lumidigm discloses “*one or more processors configured to receive one or more signals from the at least one of the photodiodes and determine measurements of oxygen saturation of the user*” for the reasons discussed above for ’502 claim 19, limitation [19E].

(b) ’648 Patent, Claim 24

Lumidigm discloses ’648 claim 24, which recites “*[t]he user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping*” for the reasons discussed above for ’501 claim 1, limitation 1[E] and ’502 claim 28, limitation [28F]. Although this claim references “substantially preventing light piping,” rather than “reducing” or “avoiding light piping,” the same reasoning applies. Tr. [Warren] 1228:16-23. Lumidigm explains that “the body of the sensor head,” which includes the protrusion, is made from “optically opaque material” and that the detectors are recessed from the sensor surface in this optically opaque material to provide “optical blocking” and to “minimize” “shunted” light and other unwanted light from reaching the detectors. RX-0411 at 7:64-8:10. Lumidigm further

the quality of the signal,” create “positive contact with a body surface,” and make the pulsatile sigla “more available to the field of view of the sensor.” Tr. [Warren] 145:1-1246:12; RX-0666 [Seiko 131] at 3:22-28 (“When the outside surface of the light transmittance plate is a convex surface ... positive contact between the body surface and outside surface of the light transmittance plate can therefore be improved.”), 19:5-8, Fig. 28; RX-0670 [Cramer] at 5:45-51 (describing convex boss region as “resulting in not only effective sensing ... but minimum discomfort to the wearer”), Figs. 3 and 6; *see also* Tr. [Warren] 1194:15-1195:5, RDX-8.12 (showing protrusions in the prior art, including RX-0473 [Smart] at Fig. 1, RPX-006 [Kansas State 6D]).

Non-infringing alternatives are irrelevant. Complainants argue that the existence of non-infringing alternatives to the asserted claims of the Poeze Patents demonstrates they are not obvious. But existence of non-infringing alternatives is not a recognized secondary consideration. *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013) (“Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention.”).

No industry praise or long-felt but unmet need. Complainants have not presented any evidence of industry acceptance or praise, licensing, or a long-felt but unmet need with respect to the Poeze Patents.

2. Invalidity Under 35 U.S.C. § 112

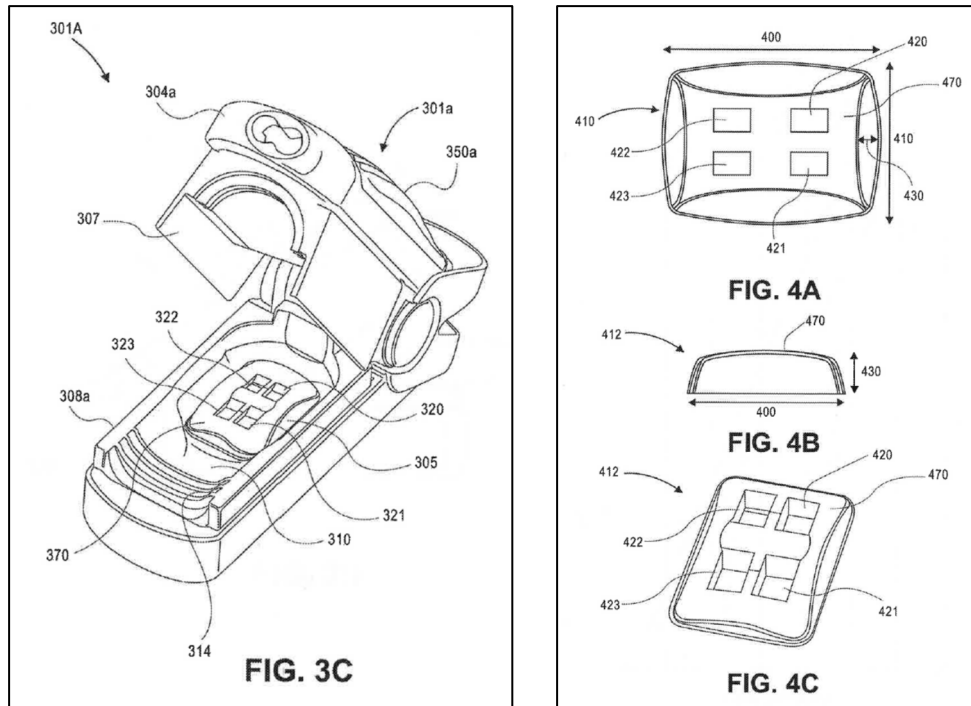
The asserted Poeze claims are also invalid under 35 U.S.C. § 112.

To begin, there are no embodiments in the Poeze specification that disclose the claimed combinations of elements. Instead, the claims are cobbled together from multiple embodiments in

a manner insufficient to satisfy the written description requirement. *Flash-Control, LLC v. Intel Corp.*, No. 2020-2141, 2021 WL 2944592, at *3-4 (Fed. Cir. July 14, 2021) (“[T]he specification must present each claim as an ‘integrated whole.’ ... A patent owner cannot show written description support by picking and choosing claim elements from different embodiments that are never linked together in the specification.”); *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (“an amalgam of disclosures plucked selectively from” an application did not satisfy Section 112 because no disclosure described claim “as an integrated whole”).

All of the asserted claims require (a) multiple LEDs, (b) multiple photodiodes, and (c) a protrusion with a plurality of openings, positioned or arranged over the photodiodes, each of which includes an opaque lateral surface or is lined with an opaque material, along with other limitations. No embodiment in the Poeze specification discloses this combination of elements. *E.g.*, Tr. [Warren] 1246:24-1247:7 (confirming no embodiments include claimed combinations, noting that “[a]s an example, the combination of three LEDs, three photodiodes, and a plurality of openings over the photodiodes with opaque lateral surfaces as in [’501 patent] claim 12, I can’t find a single embodiment,” and “[t]he same is true” for the other independent claims); RDX-8.131 (describing relevant limitations).

For example, while the Poeze Patents disclose, in Figures 3 and 4, an embodiment with three or more photodiodes and a protrusion with openings over those photodiodes, neither these embodiments, nor any others, show the claimed combinations of elements:

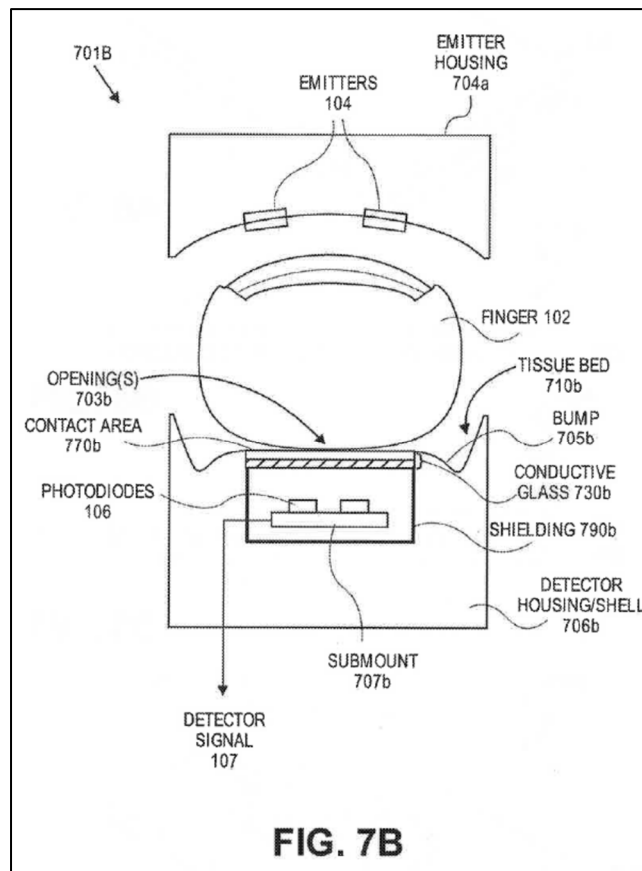


JX-001 [’501 patent] Fig. 3C; *see also* Tr. [Kiani] 99:17-100:3 (discussing Figure 3C). These figures have an “emitter shell,” but no disclosure of what is *in* that shell and no disclosure anywhere of the specific arrangement of three LEDs (recited by ’501 claim 12); the specific arrangement of a “plurality” of LEDs or emitters (recited by ’502 claim 22 and ’648 claims 24 and 30); or the specific arrangement of “sets” of LEDs (recited in ’502 claim 28 and ’648 claim 12). The specification also provides minimal details about the openings in this embodiment; it states that the protrusion can have openings, and that the openings can have windows, but it does not disclose *any* openings with opaque lateral surfaces or lined with opaque material (recited in all independent claims). *E.g.*, JX-001 [’501 patent] 19:38-67, 23:61-24:8. Accordingly, none of the claims is presented as an “integrated whole” in the specification, and the claims are therefore invalid for lack of written description.

In his rebuttal testimony, Dr. Madisetti cited portions of the patent specifications in support of *individual* claim limitations regarding multiple LEDs, three or more photodiodes, and opaque

lateral surfaces, and suggested that a POSITA would have understood that these disclosures of elements of different embodiments could be combined to yield the claimed combinations—but cited *no* embodiments containing the actual combinations of limitations covered by the asserted claims. *See* Tr. [Madisetti] 1347:14-1349:6.

Dr. Madisetti focused, in particular, on Figure 7B:



JX-001 [’501 patent] Fig. 7B (cited on CDX-0012C.044). But Figure 7B discloses only two emitters and two photodiodes. It also describes only a *single* opening over the photodiodes—not the *multiple* openings required in the asserted claims. *See* Tr. [Madisetti] 1347:14-1349:6.

Dr. Madisetti also cited a generic reference to implementing the features of the sensor in Figure 7B “with any of the sensors 101, 201, 301 described above.” CDX-0012C.044 (quoting JX-001 [’501 patent] at 26:25-29). But this disclosure, merely indicating a mix-and-match

approach to the embodiments, is insufficient. *See Flash-Control, LLC*, 2021 WL 2944592, at *4 (“The written description requirement is not met when, as here, the specification provides at best disparate disclosures that an artisan might have been able to combine in order to make the claimed invention.”).²⁴

There are additional defects specific to particular claims and limitations.

'502 claim 22 is invalid for lack of written description. The specification nowhere discloses “at least *four emitters*” that each “comprise[] a respective *set of at least three LEDs*” as claim 22 requires. Tr. [Warren] 1247:8-12 (confirming no discussion or embodiments with these elements). In rebuttal, Dr. Madisetti again pointed to Figure 7B and the specification’s separate disclosures of “emitters 104” with “sets of optical sources” (Tr. [Madisetti] 1349:7-1350:3, 1350:22-1352:4), but he failed to identify any specific support for *four* emitters that each contain a set of at least *three LEDs*. Accordingly, the specification does not convey that the inventors actually possessed this element as of the '502 patent’s alleged priority date.

'502 claim 28 and **'648 claim 12** are also invalid for lack of a written description. The common specification fails to disclose anything regarding separate *sets of LEDs* that each have LEDs emitting light at a “*first wavelength*” and “*second wavelength*” as '502 limitations [28A] and [28B] and '648 [8A] and [8B] require. *See* Tr. [Warren] 1247:13-17 (confirming no discussion of these elements). In rebuttal, Dr. Madisetti again pointed to the specification’s disclosures of “emitters 104” with “sets of optical sources,” (Tr. [Madisetti] 1349:7-1350:3, 1350:22-1352:4),

²⁴ Furthermore, while Dr. Madisetti’s testimony is insufficient to show the Poeze Patents satisfy the written-description requirement, his acknowledgement that a POSITA would have expected it was possible to implement the claimed elements in a variety of arrangements—even those not disclosed—supports Apple’s position on obviousness. As discussed above, a POSITA would have been motivated to and had a reasonable expectation of success combining teachings of Lumidigm with one another and with the other references discussed above, particularly as Lumidigm itself expressly suggests doing so.

but he failed to identify any support for sets of LEDs that *each* had LEDs emitting light at a “first wavelength” and “second wavelength.” Accordingly, the ’502 and ’648 patent specification does not convey that the inventors actually possessed these elements.

’502 claim 28 is also invalid for lack of enablement. ’502 claim 28 requires a “user interface comprising a *touch-screen display*, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user” [28K]. The ’502 specification, however, does not provide any guidance to enable any user-worn device with a “touch-screen display” that “displays indicia responsive” to any “measurement.” Tr. [Warren] 1247:18-23 (confirming that “two brief references to touchscreens” in the Poeze Patent specification would not tell a POSITA how to implement a user interface with a touchscreen). Moreover, none of the references in the ’502 patent to a “touch-screen display” enables including the touch screen in a user-worn device. *Id.* In short, the specification does not teach a POSITA how to make and use an invention with such elements. In rebuttal, Dr. Madisetti did not explain how a touch-screen display would have been *enabled*, but instead discussed only the instances in which a touch-screen was briefly *mentioned* in the specification. Tr. [Madisetti] 1352:5-24. Dr. Madisetti made no effort to explain how such passing reference would have been sufficient for enablement.

Finally, ’501 claim 12, ’502 claim 28, and ’648 claim 24 are invalid for lack of enablement, and ’648 claim 24 is further invalid for lack of written description. ’501 claim 12 and ’502 claim 28 require that the openings in the protrusion include or are defined by opaque surfaces to “avoid” or “reduce” “light piping.” ’501 limitation [1E]; ’502 limitation [28F]. ’648 claim 24 requires that “the protrusion comprises opaque material configured to substantially prevent light piping.” [24]. But the specification provides no guidance to a POSITA on how to manage the problem of

investments. The table also includes a cross reference to the following sections where these issues are discussed in more detail.

Flaws in Complainants' Economic Prong Calculations	Effect on Economic Prong Analysis
Tr. [Young] 516:1-16; Tr. [Thomas] 1289:20-1292:16.	Complainants claimed [REDACTED] should not be counted. Sections VII.A.1.c.(1), VII.B.1.d.(1), <i>infra</i> .
Tr. [Thomas] 1293:13-1295:10; Tr. [McGavock] 538:4-15.	Complainants claimed expenditures for [REDACTED] should not be counted. Sections VII.A.1.c.(2), VII.B.1.d.(2), <i>infra</i> .
No basis or documentary support for [REDACTED] Tr. [Thomas] 1291:1-9 1295:11-1296:18 (executive time estimates), 1298:4-1299:5 Tr. [McGavock] 560:6-561:12.	Claimed [REDACTED]. Sections VII.A.1.c.(1), VII.B.1.d.(1), (3), (6), <i>infra</i> .
Cost models used to project future expenditures for [REDACTED] [REDACTED] lack any supporting basis or documentation. Tr. [Thomas] 1294:21-1295:10.	Expenditures for the identified categories should not be counted. Sections VII.A.1.c.(3), VII.B.1.d.(2), (4), (5), (8), <i>infra</i> .
Appendices (and the estimates they contain) were prepared for this Investigation by Masimo and Cercacor executives [REDACTED] Tr. [Young] 486:8-15, 493:14-494:17; RX-1211C [Young] 97:4-97:17.	Underscores the need for independent validation and contemporaneous documentation to support the calculations.

Accordingly, because the accuracy and reliability of Complainants' appendices are unsubstantiated and Mr. McGavock admittedly did almost nothing to independently validate those calculations, the ALJ should find that Complainants have failed to establish a significant investment in plant and equipment under subsection (A). Satisfaction of the economic prong should not be based solely on litigation-created documents without even a modicum of supporting contemporaneous documentation, testimony, or independent expert validation.

b. Complainants Improperly Rely on Post-Complaint Evidence.

As set forth above in Section III, Complainants neither alleged in their pre-hearing brief nor presented evidence at the hearing of the requisite “significant and unusual developments” to justify consideration of post-complaint activities and investments. *Thermoplastic Motors*, Inv. No. 337-TA-1073, Comm’n Op. at 7. Accordingly, all activities and developments after July 7, 2021 should be disregarded (under both subsections (A) and (B)). Apple nonetheless identifies additional substantive reasons to disregard those expenditures below.

c. Complainants’ Claimed Expenditures Are Overstated.

As discussed above in Section VII.A.1.a, the source appendices are rife with unsupported calculations that markedly overstate Complainants’ investments in plant and equipment. Flaws with each of Complainants’ calculations (reflected in the upper half of Mr. Thomas’s Schedule 3 (RX-1462C)) are discussed below.

(1) [REDACTED]

Complainants claim amounts for expenditures [REDACTED]
[REDACTED] RX-1462C; Tr. [Young] 497:1-20, 517:2-8, CDX-0006C.021;
Tr. [McGavock] 560:6-10; CDX-15C.006. But these alleged expenditures are unreliable and should not be counted. Tr. [Thomas] 1289:20-1292:16, 1301:6-1302:2.

Although Complainants attribute [REDACTED] of these costs to the “Masimo Watch” articles, Complainants present no evidence indicating that any of these undocumented and unexplained

[REDACTED]

[REDACTED] Tr. [McGavock] 560:11-15. Instead, Complainants’ CFO, Mr. Young, confirmed that the claimed [REDACTED]

[REDACTED]

[REDACTED]

Tr. [Young] 515:16-25. Mr. Young likewise confirmed that the claimed [REDACTED]
[REDACTED] Tr. [Young] 515:12-
516:16; *see also* Tr. [Thomas] 1289:20-1292:16.

Additionally, although Complainants characterized their [REDACTED]
[REDACTED] (Tr. [Opening] 19:12-20), none of Complainants' witnesses
offered any explanation of the relationship between [REDACTED]
[REDACTED] had any bearing on the development of
the Masimo Watch. To the contrary, Complainants' chief engineer, Mr. Al-Ali, could not even
identify which products or projects were encompassed by Complainants' [REDACTED]
[REDACTED] (RX-1196C [Al-Ali Dep.] 162:9-163:1; Tr. [McGavock] 561:2-12) and
confirmed that Masimo [REDACTED]
[REDACTED] (Tr. [Al-Ali] 337:17-21). Nor is there any evidence outside of a line item in an
appendix to support the amounts that Complainants are claiming for [REDACTED] or
that identifies the activities that Complainants claim comprise [REDACTED] *See* Tr.
[Young] 517:2-23; CX-0640C [Appendix M], Summary tab, row 11 (using hard-coded allocation
percentages).

Accordingly, because the amounts identified as attributable to [REDACTED]
[REDACTED], and because Complainants failed to allocate any
portion of those expenditures to [REDACTED] none of Complainants'
[REDACTED] should be counted under subsection (A). *See, e.g., Certain Digital
Media Devices*, Inv. No. 337-TA-882, ID at 450 (July 7, 2014) (rejecting claimed investments
attributed to "product lines that include, but are not limited to the DI Products.").

(2) Manufacturing

[REDACTED]

Complainants claim a portion of the [REDACTED]

[REDACTED] See RX-1462C; CDX-15C.006;
Tr. (McGavock) 539:16-24. The pre- and post-complaint amounts are unreliable and should not
be counted. See Tr. [Thomas] 1292:17-1294:20, 1301:6-1302:2.

With respect to the manufacturing expenditures from Q1 2021, Complainants have failed
to identify any evidence that they conducted a [REDACTED]

[REDACTED] Instead, Complainants appear to have derived [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Tr.
[Young] 489:10-16. But outside of a single tab of an appendix using hard-coded values (CX-
0629C [Appendix A], [REDACTED] there is no documentary support [REDACTED]

[REDACTED] Complainants did not explain how the utilized
square footages identified in the appendix were determined or whether the space was actually used
for [REDACTED] CX-1202C [Kaufman Dep.] 71:12-19. The source
appendix indicates that [REDACTED]

[REDACTED]
CX-0629C [Appendix A], [REDACTED]
[REDACTED] Nor is there any
documentation supporting [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

announced on February 15, 2022 (CX-1637), long after the Complaint was filed. As such, the acquisition has no bearing on evaluation of Complainants' asserted domestic industry as of the time of the Complaint. **Second**, Mr. McGavock's description of it as [REDACTED] (Tr. [McGavock] 544:9-14) implausibly attributes the full acquisition cost as an investment in distribution for the Masimo Watch. Mr. Young acknowledged that Masimo obtained multiple "premium audio brands like Denon, Marantz, Bowers & Wilkins, as well as Polk Audio" as part of the deal. Tr. [Young] 483:1-9. Masimo's own financial summary shows those brands generate some \$900 million in annual revenue and a \$125 million earnings stream. CX-1637 at 19; Tr. [Thomas] 1303:17-1304:21. Mr. McGavock provided no analysis of the amount of the acquisition cost that could be plausibly attributed to commercialization of the Masimo Watch. Accordingly, Complainants' acquisition of Sound United is not an appropriate indicator of either quantitative or qualitative significance for the Masimo Watch.

e. Complainants Improperly Aggregated Domestic Industry Expenditures.

Under the technical prong, Complainants have identified five articles as practicing the '501, '502, '648, and '745 patents, one article practicing only the '501, '648, and '745 patents, and two more articles as practicing only the '745 patent. *See* RDX-9.5C; Tr. [Madisetti] 676:4-12, CDX-0011C.0008. Complainants' economic prong analysis (under both subsections (A) and (B)) addresses a singular "Masimo Watch Product," improperly considering all eight articles in the aggregate. Tr. [McGavock] 538:20-539:1 ("I organized my analyses around the Masimo Watch, which I understand is covered by four patents ..."); Tr. [Thomas] 1306:20-1307:18; *Certain Electronic Stud Finders*, Inv. No. 337-TA-1221, Comm'n Op. at 48 (Mar. 14, 2022) (expenditures may not be aggregated across products practicing different asserted patents). Nor do Complainants

[REDACTED]

[REDACTED]

provide the information necessary to allocate expenditures to the different articles. Tr. [Thomas] 1306:20-1307:18. In the absence of a reliable basis for attributing the aggregated expenditures to the distinct set of claimed DI products, no quantification is possible. *Electronic Stud Finders, supra.*

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

COMPLAINANTS' REPLY POST-HEARING BRIEF

[REDACTED]

argument on its narrow view of the terms: (1) “arranged over”/“positioned over”/“above” and (2) “openings”/“through the protrusion”/“through holes.” AppleIPHB 26-40. But Apple never provided its narrowing constructions in its IPHB or anywhere else.

By failing to specify or apply consistent constructions, one is forced to deduce them from Apple’s arguments. See *Albrechtsen v. Bd. of Regents of Univ. of Wisconsin System*, 309 F.3d 433, 436 (7th Cir. 2002) (“Courts are entitled to assistance from counsel....”). Apple’s strategy was to cast its legal construction arguments into factual disputes. But claim construction is a question of law.

Apple also blames Madisetti for not applying Apple’s unstated constructions, alleging that he “ignored the additional requirements” (AppleIPHB 32) and “effectively ignored the requirement.” AppleIPHB 34. Madisetti did not ignore anything. He applied the plain meaning of these terms in view of the intrinsic evidence, properly applied those constructions, analyzed the evidence, and rendered his opinions.

1. “arranged over”/“positioned over”/“above”

Apple argues “arranged over”/“positioned over”/“above” in the claims refer to the position of the components relative to gravity. AppleIPHB 26-33. Apple relies on the design and operation of the Accused Products to interpret the claims. But construing claims in light of the accused devices is error. *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (en banc). Apple’s overly narrow construction also ignores the intrinsic evidence. The Multi-Detector Patents’ disclosure describes devices that work in any orientation. JX-0001 at 8:21-23, 10:15-27, 10:62-11:3, 11:45-55. Thus, the term “over” is not tied to gravity.



Masimo explained in detail the reasons why “arranged over”/“positioned over”/“above” in the claims, specification, and extrinsic evidence refer to the configuration of features of the device relative to each other, not the position of the device relative to the Earth. MasimoIPHB 42-49.

Apple argues that “over” is vertically above relative to gravity. AppleIPHB 28 (contrasting face-down Apple Watch orientation to MDP’s transmissive, finger-worn embodiment). But the specification imposes no such requirement. Indeed, the specification describes different measurement sites including “a finger, toe, hand, foot, ear, forehead, or the like.” JX-0001 at 8:21-23, 10:64-66 (“any location on a patient’s body”), 11:45-48. And as Warren conceded, the patents’ specification expressly teaches that “[i]n some embodiments, the measurement site 102 is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person’s left arm or left hand.” Tr. (Warren) 1277:21-1278:8. These different measurement sites involve different positions and orientations. The specification places no requirement on device orientation when taking a measurement. Thus, its use of the term “over” is never restricted to Earth’s gravitational center.

Further, the concept of “over” for a pulse oximeter sensor being based on gravity makes no sense at the time of filing. Pulse oximeter sensors, like Masimo’s devices, take measurements regardless of the orientation, as shown below.



CX-1371 at 56; CX-0691 at 3. Apple identifies no evidence that a POSITA *at the time of filing* would consider the term “over” in describing a pulse oximetry sensor as having any gravitational position requirement. *Trading Techs. Int’l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1351 (Fed. Cir. 2010) (claims are interpreted from perspective of POSITA as of the priority date). Nor has Apple identified any pulse oximeters from the “time of filing” that restricted operation based on gravity. That Apple now claims some vague gravitational requirement for the Apple Watch does nothing to inform what a POSITA would have understood the term “over” to mean for a pulse oximeter sensor in the Multi-Detector patents in 2008.

Not surprisingly, Apple’s patents on its Watches also use the term “over” unrelated to gravity. MasimoIPHB 46-48. The intrinsic and extrinsic evidence, Apple’s own patents, and the

[REDACTED]

case law makes clear that the terms recite the configuration of features of the device relative to each other. *See* MasimoIPHB 42-49.

2. “openings”/“through the protrusion”/“through holes”

Apple narrowly construes “openings”/“through the protrusion”/“through holes” to require an “absence of material.” AppleIPHB 34-39. Apple points to nothing in the claim, specification or any extrinsic evidence to support Apple’s narrowing construction. To the contrary, the evidence contradicts Apple’s arguments.

The Multi-Detector Patents’ disclosure teaches the openings can be made from glass or other transparent material. *See, e.g.*, JX-0001 at 8:26-29, 27:22-26, FIG. 7B. Glass or other transparent material is not an “absence of material.” Masimo also presented extensive evidence explaining that the “openings”/“through the protrusion”/“through holes” in the patents refer to the passage of light, and not physical or tangible objects. MasimoIPHB 49-53 (citing JX-0001 at 8:26-29, 19:38-53, 27:22-26; Tr. (Madisetti) 702:8-703:10).

Apple alleges “Madisetti’s interpretation appears to conflate the meaning of ‘opening’ or ‘through hole’ with the separate term ‘window’” AppleIPHB 37-38. Apple relies on its own fact witness, Block’s deposition testimony, to provide “opening” with an alleged plain and ordinary meaning of “the fact that light can pass through something does not mean that it’s an opening.” AppleIPHB 37 (citing CX-0281C (Block) 272:10-17). But Block’s self-serving opinion does not inform what a POSITA would have thought in 2008, and was made with respect to “windows” in the Series 6. CX-0281C (Block) 271:21-272:17.

Madisetti supported his opinion on a POSITA’s understanding by explaining the specification teaches “[t]he *openings* can be *made from glass* to allow attenuated light from a

[REDACTED]

[REDACTED] Tr. (Al-Ali) 262:7-263:10, 264:6-264:13, 268:22-271:18, 272:16-278:13, 313:14-318:22; CX-0378C; CX-0433C; CX-0370C; CX-0494C.⁶

The undisputed evidence showed that the Masimo Watches indeed calculate oxygen saturation, very accurately. MasimoIPHB 86-87, 99-101. Apple falsely represents that the only demonstrations of record were those done for or by Apple's experts, but CX-0836C contains the results of Scruggs' demonstrations for Madisetti confirming the devices were still calculating oxygen saturation. Notably, Apple's experts never affirmatively opine that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Apple continues to ignore [REDACTED]

[REDACTED]

⁶ Apple apparently claims it is implausible that Masimo—the world's best-in-class pulse oximetry provider whose products are used on over 200 million patients a year and whom Apple wanted to mine for its technology—could successfully measure oxygen saturation continuously at the wrist. Perhaps that is because Apple failed to achieve reasonable accuracy despite (1) hiring many engineers from Masimo, (2) hiring a 20-year veteran of pulse oximetry design from Nellcor to replace Dr. Lamago, (3) having an army of "Ph.D.s" dedicated to the project, and (4) employing a team who spent [REDACTED]



CX-0378C at 32; *see also* CX-0494C; Tr. (Al-Ali) 272:16-277:13, 315:16-317:20.

Thus, Apple presents no evidence to rebut Masimo’s showing on the functionality and operation of the Masimo Watches. Apple also challenges several claim features because its experts could not “visually” confirm the presence of the elements inside the watch. But, this ignores the testimony and extensive corroborating documents exhibiting these features.

1. Domestic Industry Articles [REDACTED]

Masimo relies on [REDACTED] and W1 for the Multi-Detector Patent claims. The un rebutted evidence shows that [REDACTED] (CPX-0052C), [REDACTED] (CPX-0019C), [REDACTED] (CPX-0058C), and [REDACTED] (CPX-0065C) [REDACTED], and that [REDACTED] (CPX-0020C) and the W1 [REDACTED]

Apple attempts to challenge Masimo’s evidence of [REDACTED] (CPX-0052C) due to a [REDACTED]

[REDACTED] AppleIPHB 174. But Scruggs explained [REDACTED]

[REDACTED]

[REDACTED] Tr. (Scruggs) 476:10-477:1. Al-Ali testified watches with [REDACTED]

[REDACTED] Tr. (Al-Ali) 261:20-262:25, 263:6-13. This evidence confirms [REDACTED]

[REDACTED] Moreover, [REDACTED]

[REDACTED]

(d) **“Windows”/“Optically Transparent Material” Therein**

(Applies to: ’502 [19D], [28G]; ’648 [8F], [20D])

Apple argues “optically transparent material” or “transmissive windows” in openings over photodiodes were “well-known” and disclosed by Lumidigm, Seiko 131, and Cramer. AppleIPHB 111-113. Apple also refers to Warren’s testimony about “State of the Art” examples and Lumidigm. *Id.* at 111. Warren testified “I really like” Cramer, Nippon, Seiko 131, Haar, and a rudimentary Kansas State device (RX-0648). Tr. (Warren) 1193:24-1194:14, 1221:16-1222:9. But he did not identify where any of those “disclosed” a window (or any other feature). *Id.* Such conclusory testimony does not establish the claimed windows were “well-known.” *Koito*, 381 F.3d at 1152. Furthermore, Apple represented to the ALJ “that the additional prior art references identified in its prehearing brief will not be relied upon as grounds for anticipation or obviousness” Doc. ID 772058 (Order No. 40) at 1-2. Thus, the ALJ need not consider them in evaluating any ground.

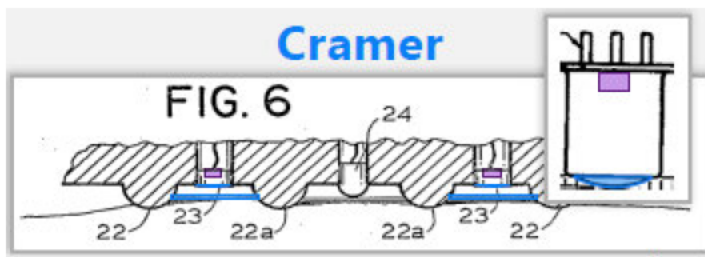
Regardless, none of these references disclose windows as claimed. For example, Nippon, Haar, and Kansas State do not teach a protrusion comprising a convex surface. RX-0665 at FIG. 3b; RX-0667 at Fig. 2; RX-0648. Nippon, Haar, and Kansas State thus do not have openings in the claimed protrusion, much less any windows in protrusion openings. *Id.*

Lumidigm, Seiko 131, and Cramer also fail to disclose the claimed windows for the reasons discussed below. Lumidigm does not disclose windows in a convex protrusion at all because Lumidigm does not disclose a protrusion or openings as claimed. MasimoIPHB 138-139. Furthermore, a POSITA would not have understood Lumidigm’s vaguely mentioned “optical relays,”—including a “fiber optic face plate,” “fiber bundle,” or “optical relay units”—to be windows for inclusion in openings over detectors. *Id.* Cramer and Seiko 131 do not disclose the

claimed windows because neither reference discloses a protrusion or openings as claimed. *Id.* at 144-150. Masimo, therefore, has already explained why Lumidigm, Seiko 131, and Cramer fail to disclose the claimed windows.

Apple raises two additional arguments that further reveal the prior art does not disclose the claimed windows. First, like its analysis for the light-piping-related claim elements (discussed above), Apple’s analysis of Cramer for these claim elements relies on what a POSITA allegedly would have understood from “the data sheet for the CLT 2160 referenced in Cramer’s specification.” AppleIPHB 112 (citing RX-0670 at 5:33-35). The ALJ should reject that argument for the reasons explained above.

Second, Apple now relies on another doctored image (below) to argue Cramer “has a further layer of clear transparent windows between the cans and the tissue”:



RDX-0008.74 (annotating RX-0670 at FIG. 6 and RX-1221 at 1, including by drawing in alleged windows in blue and alleged photodiodes in purple which are shown nowhere, and adding a “callout” from a different source)¹²; AppleIPHB 113.

The bottommost blue lines Warren added are particularly misleading. Those lines correspond to the portion of the annular rings or bosses, not to any separate structure over the detectors of Cramer. Those blue lines are actually the rings (22/22a) behind the cross section.

¹² The above figure is yet another example of an edited figure taken from Warren’s demonstratives for which Apple deceptively cited to the reference only without conveying it had been modified. AppleIPHB 113.

Comparing Apple's demonstrative (below, top) of FIG. 6 of Cramer with FIG. 3 of Cramer (below, bottom), which are figures showing the same sensor from the same perspective, shows that the "further layer" of windows identified by Apple does not exist.

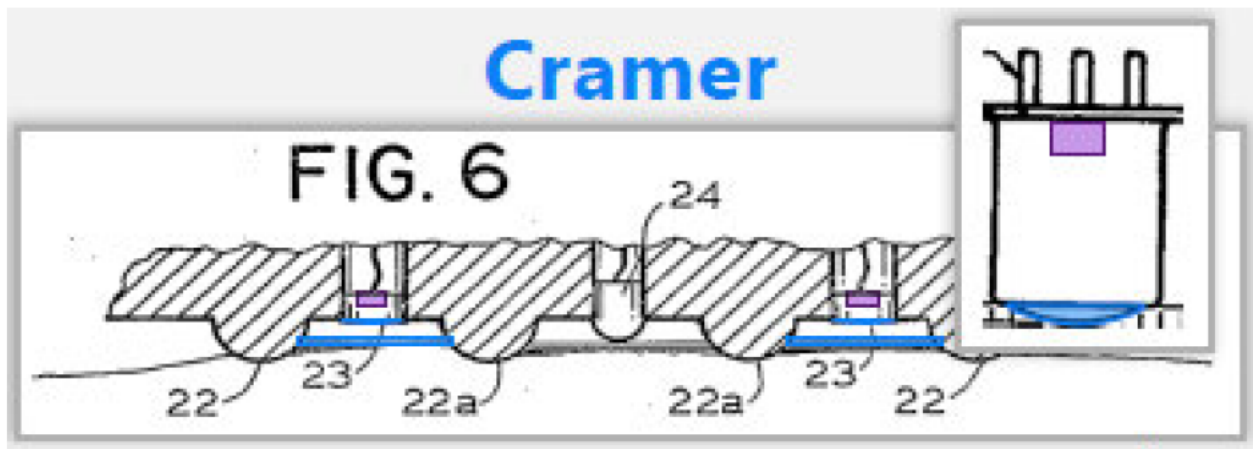
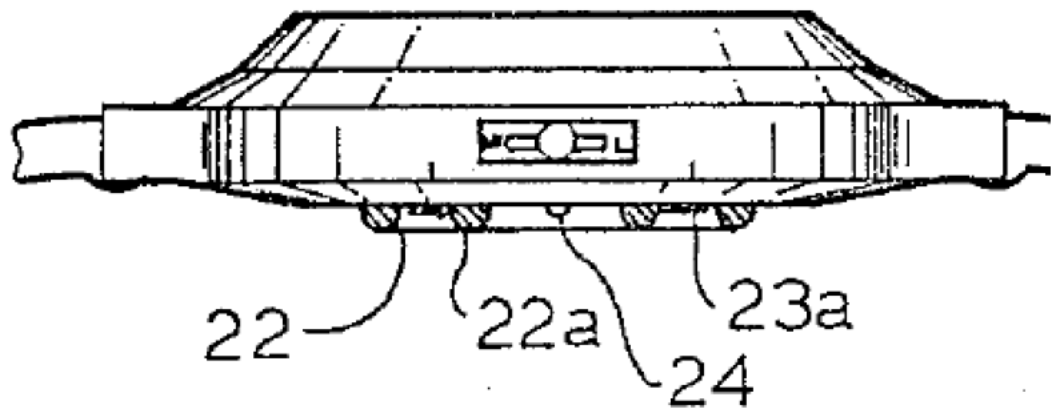


FIG. 3



And even if the ALJ credits Warren's artistic license, the blue lines, as drawn, would be a single window in an annular shape in the space between the two annular bosses (22/22a). That imaginary structure fails to disclose *multiple* "windows" or transparent material in *multiple* "openings."

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MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S REPLY POST-HEARING BRIEF

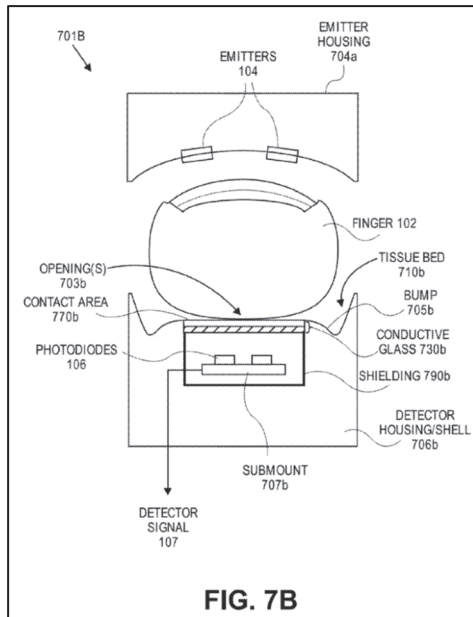
2. Invalidity Under 35 U.S.C. § 112

Before attempting to rebut Apple’s invalidity arguments under Section 112, Complainants argue that those positions “are in tension with [Apple’s] anticipation and obviousness defenses” because Apple supposedly “relies on scant disclosures from Lumidigm” while “ignor[ing] the detailed disclosures” of the Poeze Patents. CIB 175. In fact, the exact opposite is true. As detailed in Apple’s Post-Hearing Brief, Lumidigm would have fully disclosed each claim limitation to a POSITA. By contrast, the claims of the Poeze Patents are disconnected from the specification, because Complainants were forced to stretch the specification to its breaking point in an attempt to draft claims to cover Apple Watch Series 6 that had *already been released to the public*.

Complainants also ignore their own vulnerabilities to this same argument; to the extent Complainants insist that a POSITA would have found written-description support or enablement based on the scant disclosures in the Poeze specification, Complainants cannot also contend that a POSITA would have been blind to the far clearer and more robust disclosures in the prior art, including Lumidigm.

a. Claimed Combinations of LEDs, Photodiodes, and Openings

Complainants attempt to rebut Apple’s argument that no embodiment includes the recited (a) three or more LEDs or sets of LEDs, (b) three or more photodiodes, and (c) a protrusion with a plurality of openings, positioned or arranged over the photodiodes, each of which includes an opaque lateral surface or is lined with an opaque material. CIB 176-180. Complainants rely primarily on Figure 7B:



JX-0001 Fig. 7B. But as Apple has explained, this figure discloses only *two emitters* and *two photodiodes*, and describes only a *single* opening over the photodiodes—not the *multiple* openings required in the asserted claims, *each* with separate opaque lateral surfaces. RIB 150 (citing Tr. [Madisetti] 1347:14-1349:6). Predictably, Complainants rely on a string of citations relating to the description of the protrusion in *other* parts of the specification (including the distinct disclosure for Figures 3 and 4), and insist that the “specification repeatedly links the embodiments together.” CIB 178. But these “links” are scant. The primary citation offered by Complainants, JX-0001 6:65-7:8, relates to the front-end circuitry in Figures 15I and 15L, which are facially irrelevant to the asserted claims. Complainants cite other portions of the specification that purport to link together the various embodiments, but those links provide no explanation of how the Figure 7B embodiment could even fit or be modified to incorporate all the additional components Complainant suggests adding from Figures 3 and 4. CIB 178 (citing JX-0001 26:21-29 (stating in passing that “[t]he features of the sensors 701 can be implemented with any of the sensors 101,

201, 301 described above”). Instead, Complainants’ best effort to defend the claims serves only to confirm that they are cobbled together limitations from separate embodiments.

b. Other Section 112 Issues

Separate Sets of LEDs Each with LEDs Emitting at a “First Wavelength” and “Second Wavelength.” Complainants identify no specification support for these limitations. Instead, Complainants cite an assortment of passages merely mentioning “emitters.” CIB 179-180. The only relevant cited disclosure appears to be JX-0001 at 12:9-12, but that language merely describes that the sets of LEDs are capable of emitting at different wavelengths—not that *each of the two sets* actually contains one LED that emits light at a *first* wavelength and another LED that emits light at a *second* wavelength, as the claims require. ’502 claim 28 and ’648 claim 12 are therefore invalid for lack of written description.

Four Emitters Each with Three LEDs. Similarly, Complainants identify nothing in the specification to show four emitters, each with three LEDs. Instead, the most that Complainants can muster are citations for multiple emitters, with no disclosure of the *number* of LEDs in each emitter set. CIB 180. Indeed, at the hearing, Dr. Madisetti pointed to Figure 7B and the specification’s separate disclosures of “emitters 104” with “sets of optical sources,” Tr. [Madisetti] 1349:7-1350:3, 1350:22-1352:4, but identified no specific disclosure of three LEDs per set—and Complainants similarly provide no such support in their brief. ’502 claim 22 is therefore invalid for lack of written description.

Touchscreen. Complainants emphasize the instances in which touchscreen displays are mentioned in the specification, just as Dr. Madisetti did during the hearing. CIB 181-182. But as Apple explained, the specification provides no guidance on *how* to use a touchscreen that “displays indicia responsive” to any “measurement,” nor does it explain *how* to implement a touchscreen in

a user-worn device. RIB 152. And beyond his conclusory testimony that “the touchscreen display and indicia of measurement are fully enabled” (Tr. [Madisetti] 1382:6-11), Dr. Madisetti offered *no* explanation of how the bare references to touchscreens would enable a POSITA to create a system meeting that limitation in claim 28 of the ’502 patent.

Light Piping. Complainants point to a variety of references to “light piping” in the specification (CIB 182-183) without explaining (as they must) how those references disclose and enable the light-piping-reduction structures *in the claims*. Significantly, ’501 claim 12 and ’502 claim 28 require that the openings in the protrusion include or are defined by opaque surfaces to “*avoid*” or “*reduce*” “light piping,” and similarly ’648 claim 24 requires that the protrusion, with a “plurality of through holes,” “comprises opaque material configured to *substantially prevent* light piping.” The disclosure regarding an extension to “increase the height of the partially cylindrical protrusion” (JX-0001 25:47-62) relates to the unclaimed protrusion of Figure 6, which does *not* include *any* openings over photodiodes configured to reduce light piping; instead, it includes a single “cylindrical lens” over *all* the photodiodes. *Id.* 24:9-20. And the “noise shield 1703” from Figure 17 is a completely different structure than the opaque portions of openings in the protrusions in the asserted claims—indeed, it is a flat sheet entirely *separate* from part of the device in Figure 17 with the “protrusion.” *Id.* 43:32-36, Fig. 17. Dr. Madisetti did *not* “explain[] that these disclosures teach how to reduce or avoid light piping” (CIB 183), nor did he explain how the specification provides guidance on when such light piping has been “avoid[ed],” “reduc[ed],” or “substantially prevent[ed].” For these reasons, ’501 claim 12, ’502 claim 28, and ’648 claim 24 are invalid for lack of enablement, and ’648 claim 24 is further invalid for lack of written description.

**UNITED STATES INTERNATIONAL TRADE COMMISSION
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**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

In the Matter of

**CERTAIN LIGHT-BASED PHYSIOLOGICAL
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COMPONENTS THEREOF**

Inv. No. 337-TA-1276

COMPLAINANTS' CORRECTED INITIAL POST-HEARING BRIEF

[REDACTED]

Scruggs introduced numerous documents reflecting the design of CPX-0021C and [REDACTED] including CX-0656C, CPX-0014a, CPX-0014, CX-0679, CX-0836C, CX-0600C, CX-1132C, and CX-0474C. Tr. (Scruggs) at 413:17-23, 414:4-15, 414:23-415:3, 415:16-23, 415:24-416:12.

(b) [REDACTED] CPX-0029C [REDACTED]

The Masimo Watch with the [REDACTED] is exemplified by CPX-0029C and its photograph CPX-0029aC. Tr. (Scruggs) at 395:7-24. [REDACTED] *id.* at 395:14-15. Scruggs described the features of this watch [REDACTED] *Id.* at 404:10-19, 404:12, 404:20-21, 404:22-24, 405:1-7. He also demonstrated this watch to both sides' experts. RX-0263C.

Scruggs introduced numerous documents reflecting the design of CPX-0029C, including CX-0658C, CX-0605C, CX-1137C, and CX-0704C. Tr. (Scruggs) at 416:13-17, 416:20-417:11.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

-

[REDACTED]

[REDACTED]

[REDACTED]

Warren admitted the way to determine the accuracy of a device is to perform an Arms calculation. Tr. (Warren) at 1277:12-20. He performed no such calculation. *Id.* [REDACTED]

[REDACTED]

Tr. at 295:9-14.

(c) [REDACTED] CPX-0052C [REDACTED]

The Masimo Watch with the [REDACTED], exemplified by CPX-0052C (photograph at CPX-0052aC), was [REDACTED]

[REDACTED]

Tr. (Scruggs) at 405:16-18. [REDACTED] *Id.* at 396:10-11. Scruggs described the features of this watch [REDACTED]

[REDACTED] *Id.* at 405:12-406:3, 406:6-11, 406:20-22. He also demonstrated operation of CPX-0052C to both sides' experts, [REDACTED]

[REDACTED] *Id.* at 418:2-7; 419:3-11; CX-0836C at 4 (below).

[REDACTED]

Scruggs testified the [REDACTED]

[REDACTED] Tr. (Scruggs) at 476:10-477:1.

Scruggs introduced numerous exhibits reflecting the design of CPX-0052C [REDACTED]
[REDACTED] including CX-0661C, CX-0813C, CX-0836C, CPX-0012C, CPX-0012aC, CPX-
0013C, CPX-0013aC, CX-0473C, CX-0591C, CX-0701C, CX-0395C, CX-1111C.
Tr. (Scruggs) at 417:11-418:7, 406:12-22, 418:11-419:2, 419:15-420:8, 420:19-22.

(d) [REDACTED] CPX-0058C [REDACTED]

The Masimo Watch with the [REDACTED] exemplified by CPX-0058C (photograph at
CPX-0058aC), [REDACTED] Tr. (Scruggs) at 397:8-9. [REDACTED]

[REDACTED]

[REDACTED] Tr. (Scruggs) at 397:9-11. [REDACTED] *Id.* at 397:24.
Scruggs described its features and operation. *Id.* at 397:8-11, 407:2-18, 407:25-408:4, 408:19.
He also explained all [REDACTED]
[REDACTED] *Id.* at 476:1-4.

Scruggs demonstrated operation of CPX-0058C. RX-0267C. This included a
demonstration working [REDACTED]
[REDACTED] *Id.* at 408:9-10. [REDACTED]
[REDACTED] *Id.* at 409:15-20.

[REDACTED]

Scruggs introduced numerous exhibits reflecting the design of CPX-0058C [REDACTED]
[REDACTED] including CX-0665C, CX-0666C, CX-0815C, CPX-0141aC, CX-0389C, CX-0536C, CX-0550C, CX-1124C, CX-0710C, and CX-0709C. Tr. (Scruggs) at 421:1-20, 422:6-423:22.

(e) [REDACTED] CPX-0019C, CPX-0020C, CPX-0065C [REDACTED]
[REDACTED]

The Masimo Watches with the [REDACTED] exemplified by CPX-0019C, CPX-0020C, and CPX-0065C, [REDACTED]
[REDACTED] Tr. (Scruggs) at 409:21-25; 410:1-4. These watches [REDACTED]
[REDACTED] Tr. (Scruggs) at 398:22-23. Scruggs described the features and operation of these watches. Tr. (Scruggs) at 408:23-409:14, 421:14-422:5. Scruggs demonstrated operation of a Masimo Watch [REDACTED] to both sides' technical experts. RX-0268C.

Scruggs introduced numerous exhibits reflecting the design of CPX-0019C, CPX-0020C, and CPX-0065C, including CX-0652C, CX-0653C, CX-0814C, CX-0654C, CX-0655C, CX-1415C, CX-0675C, CX-0676C, CX-0812C, CX-0594C, CX-1129C, CX-0551C, CX-1125C, CX-0390C, CX-0705C. Tr. (Scruggs) at 423:23-425:6, 425:15-23, 426:6-427:11.

Al-Ali confirmed CX-1634C are [REDACTED]
[REDACTED]
[REDACTED] Tr. (Al-Ali) at 313:14-314:7. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Tr. (Al-Ali) at 314:15-318:22; CX-0494C.

(f) Masimo W1 [REDACTED]

Masimo built the W1 Watch, as exemplified by CPX-0146C, CPX-0155C (photographs at CPX-0146aC and CPX-0155aC), [REDACTED] Tr. (Scruggs) at 399:1-3; Tr. (Scruggs) at 410:5-14; Tr. (Muhsin) at 350:11-22. Masimo COO Bilal Muhsin introduced an additional example of the W1 watch. Tr. (Muhsin) at 350:23-351:2, 351:17-352:4; CPX-0157C (CPX-0157aC); *see also* CPX-156aC. The W1 is Masimo's production version of the watch. Tr. (Scruggs) at 399:4-7. [REDACTED] *Id.* Scruggs described the features and operation of this watch. *Id.* at 410:9-24; 401:10-13; 410:25-411:2, 428:8-432:9.

Scruggs introduced numerous exhibits reflecting the design of the W1, including CPX-0146C, CX-0772C, CX-0784C, CX-0790C, CX-0685C, CX-1185C, CX-0806C, CX-0595C, CX-0392C, CX-0805C, CX-0801C, CX-0593C, CX-1128C. Tr. (Scruggs) at 428:8-432:9, 432:13-21.

As explained above with corresponding citations to the evidence, [REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED] Tr. (Al-Ali) at 274:15-275:3; CX-0378C at 32; CX-0494C. On the other hand, Apple's expert Warren did no Arms calculations on the clinical accuracy of any Masimo watch. Tr. (Warren) at 1277:12-20.

[REDACTED]

work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Doc. ID. 770692 ¶10.


B. Claim Construction

Apple raised two new constructions for the phrases: (1) “arranged over”/“positioned over”/“above” and (2) “openings”/“through the protrusion.” Tr. (Warren) at 1249:10-1253:3; RDX-0008.137-8.143; Apple PHB at 7-16. Apple never identified these phrases during claim construction, but rested its entire noninfringement defense on them. Apple’s construction of “arranged over”/“positioned over”/“above” incorrectly assumes the patent specified the positioning of components relative to the Earth, and not relative to each other. And Apple’s construction for “openings”/“through the protrusion” ignores the patents are concerned with the passage of light, and not physical or tangible objects. Masimo addresses the new claim construction below.

1. “Arranged Over”/“Positioned Over”/“Above”

The six Asserted Claims each recite a user-worn device with various structural elements including a protrusion comprising a convex surface. Five of the Asserted Claims also recite either a protrusion or openings in the protrusion “arranged over”/“positioned over”/“above” another structure of the user worn device:

- “a protrusion *arranged over* the interior surface, the protrusion comprising a convex surface” (’501 [1C]) and “a plurality of openings extending through the protrusion and *positioned over* the three photodiodes” (’501 [1D]);

- 
- “a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening *positioned over* a different one of the four photodiodes” (’502 [19C]);
 - “a protrusion arranged *above* the interior surface, the protrusion comprising: a convex surface” (’502 [28E]);
 - “a protrusion comprising a convex surface and” (’648 [20C]) “a plurality of through holes, each through hole including a window and *arranged over* a different one of the at least four photodiodes” (’648 [20D]).

’648 Claim 12 does not recite “arranged over”/“positioned over”/“above,” and instead it recites “aligned with.” Thus, Apple’s new claim-construction and noninfringement arguments are inapplicable to this claim.

The patent makes clear the “arranged over”/“positioned over”/“above” language refers to the configuration of features of the device relative to each other, not to the position of the device relative to the Earth. For example, the patent shows that the protrusion is arranged over the photodiodes and their interior surface by extending across that surface. *See, e.g.*, JX-0001 at FIGS. 3C, 3E, 4C, 7B. The surrounding language of ’501 Claim 12 confirms this meaning. For example, [1C] and [1D] specify “the protrusion comprising a convex surface and a plurality of openings ... and *positioned over* the three photodiodes.” ’501 [12] continues “wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a convex shape.” The claim itself therefore specifies the position of “over” by reciting that the protrusion covers multiple photodiodes and contacts the user’s skin.



The other Multi-Detector Patent claims recite similar positions of the components relative to one another and to the user's tissue:


- “four photodiodes ... configured to receive light ... attenuated by tissue of the user” (’502 [19B]) and “each opening positioned over a different one of the four photodiodes” (’502 [19C])
- “four photodiodes arranged in a quadrant configuration on an interior surface ... configured to receive light after at least a portion of the light has been attenuated by tissue of the user” (’502 [28C]) and “a protrusion arranged above the interior surface” (’502 [28E])
- “at least four photodiodes ... arranged to capture light at different quadrants of tissue of a user” (’648 [20B]) and “a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes” (’502 [20D]).

The claimed “configured to” language refers to this structural design of the “user-worn device.” Nothing in the claims, specification or prosecution history requires a position of components relative to the Earth.

Madisetti, an expert in the field of physiological monitoring technologies (Tr. (Madisetti) at 674:9-12; CX-0329), explained a POSITA would understand the claimed “protrusion, openings, and through holes are over the photodiodes and interior surface regardless of orientation when in use.” Tr. (Madisetti) at 700:15-25. As Madisetti described:

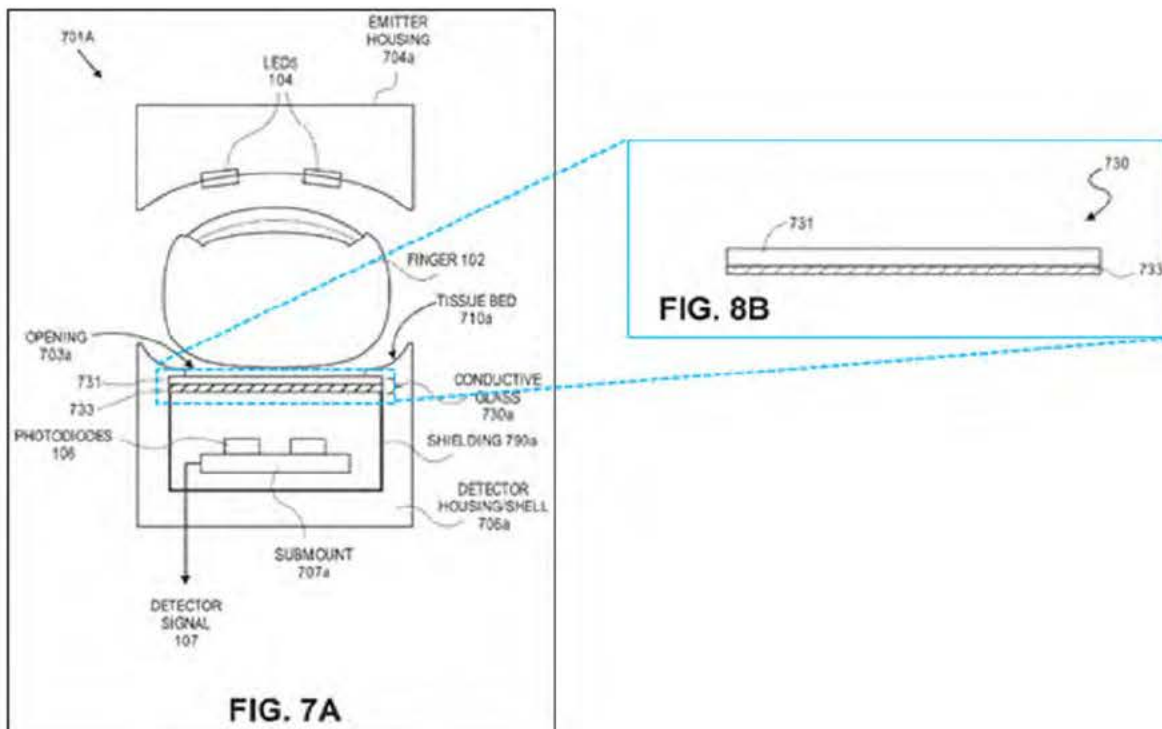
[I]f I put a Band-Aid on a scratch on my hand, for example, the Band-Aid is over the scratch, and the Band-Aid is always over the scratch [ir]respective of the orientation of my hand. So that's how one of ordinary skill in the art would understand the use of the term “over” in some of the claims that are asserted.

Id. at 701:12-18.



Apple argues “arranged over”/“positioned over”/“above” requires a “positional element” relative to the Earth when the device performs the measurement. Specifically, Apple argues the “protrusion needs to be arranged over the interior surface” *when* the Accused Products are “configured to noninvasively measure physiological parameters” and *when* the one or more processors are “configured to ... calculate a measurement of the physiological parameter of the user.” Tr. (Warren) at 1249:18-1250:10. But the phrase “configured to” in the claims refers to the design of the product, not any orientation of components relative to the Earth or its orientation during use. *See, e.g., Certain High-Density Fiber Optic Equipment*, Inv. No. 337-TA-1194, Doc. ID 740348, Final I.D. at 66 (Mar. 23, 2021) (“*In re Giannelli*, 739 F.3d 1375 (Fed. Cir. 2014) ... links the phrase ‘configured to’ to the design of a product, not its actual use.”).

The specification confirms positional words such as “above” and “over” have a meaning relative to other components, not vertically stacked with reference to Earth’s gravity. It describes small, wearable devices whose orientations are not fixed. For example, the specification describes a “conductive material 733” as being “*over* the surface of the glass layer 731.” JX-0001 at 27:59-62. Those components are shown in FIGS. 7A and 8B:

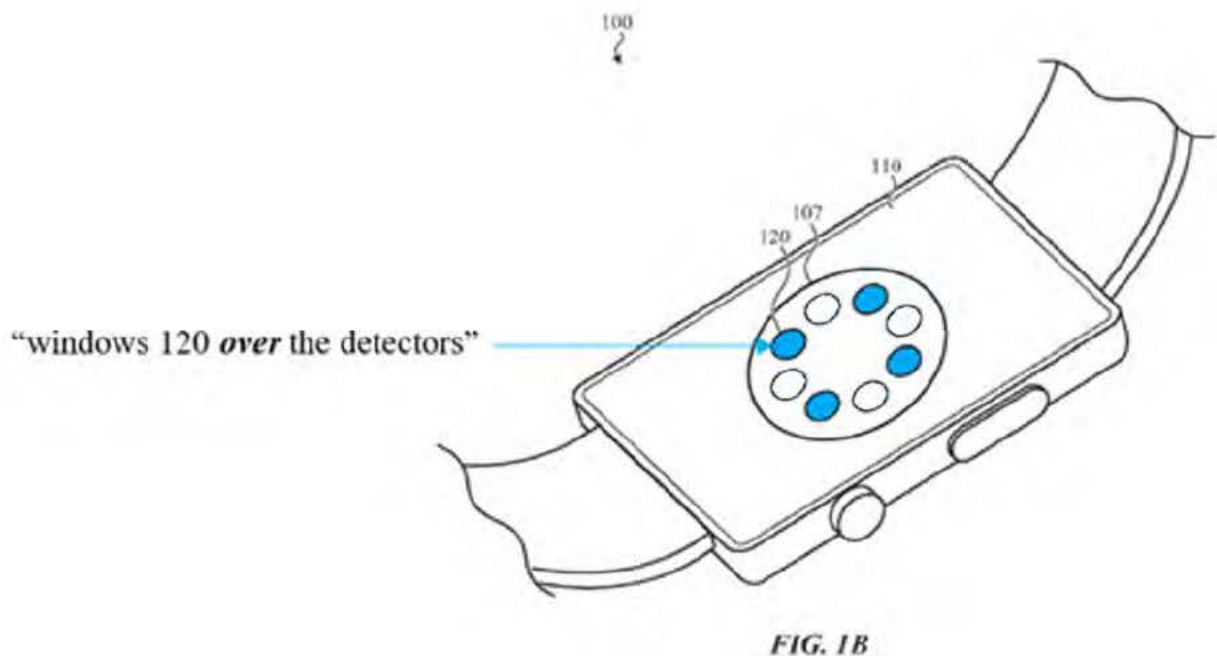


Id. at FIGS. 7A, 8B. As shown in these figures, material 733 is vertically below, not vertically above, item 731 in the associated figures, yet it is described as “over” 731. *Id.* at 27:59-62, FIGS. 7A-7B, 8A-8C. This use of “over” is consistent with Madisetti’s testimony that a POSITA would understand “over” and “above” to reference a position between the optical elements and the skin, regardless of a device’s orientation in use. *See* Tr. (Madisetti) at 700:15-25.

Apple’s own watch patents confirm the common understanding of “over” in this context as not limited to “vertically above” with respect to gravity. Dr. Ueyn Block, Apple’s corporate representative for the Accused Products’ hardware, and Dr. Vivek Venugopal, another Apple engineer, applied for a patent describing an Apple Watch-like device. CX-0118 at FIGS. 1C, 2A, 5:45-56. Their patent, consistent with Madisetti’s explanation of “over,” describes “the convex regions of the one or more protrusions may be disposed *over* the light paths of the light emitter(s) and/or light sensor(s).” *Id.* at 30:6-9, FIGS. 1C, 2A; CX-0281C (Block) at 281:8-

282:11, 283:1-6. The specification explains, “For example, a back surface may comprise a first semi-circular protrusion that extends *over* the portions of the back surface that include a first subset of the cavities and/or corresponding optical openings” CX-0118 at 32:17-23. That patent also states “FIG. 22A depicts ... a protrusion 2202 disposed *over* an optical opening 2204” and optical component 2208. *Id.* at 35:38-55, FIG. 22A.

Another Apple patent publication (CX-0103) listing Block, Venugopal, Mannheimer, and Land as inventors describes “concepts that are very similar to the Series 6 Apple Watch.” CX-0281C (Block) at 111:15-21. This publication is also consistent with Madisetti’s opinions, explaining that “windows 120 *over* the detectors may be inset within the back cover 107.” CX-0103 ¶[0065].



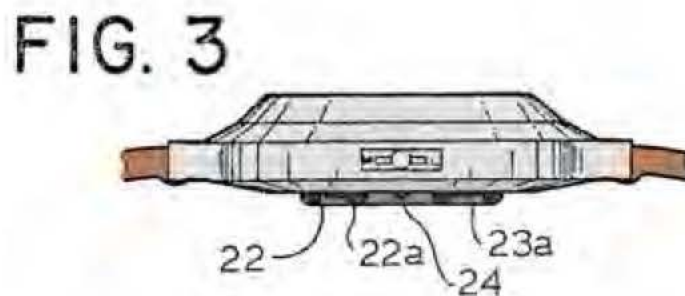
CX-0103 at FIG. 1B (annotated).

Block, Venugopal, and Mannheimer also filed a patent application describing “For example, the back surface can include ... a protrusion located *over* each of the openings.” CX-1806 ¶[0044]; *see also* CX-0291C (Mehra) at 141:22-142:8 (thermistor “on the top of the

██████████ module). Each Apple description confirms a POSITA would understand the terms “over” and “above” in the context of a wearable device refer to the relative position of the convex protrusion to the optical components beneath it, and not to Earth’s center.

Finally, when arguing invalidity, Apple evaluated references without referring to their orientation when taking a measurement. Tr. (Warren) at 1210:13-1211:8 (arguing Lumidigm “teaches” ’501 Patent [1C]), 1233:15-22 (admitting “the opening” of Seiko 131 is “*above* the photodiode in Fig. 28”). Indeed, Warren explained a photodiode “can’t detect light without some sort of opening *above* it.” See *id.* at 1193:5-6.

Apple also asserts Cramer teaches the claimed protrusion “over”/“above” the interior surface or photodiodes. Tr. (Warren) at 1246:6-12. Cramer shows “over” in the context of user-worn devices is not limited to “vertically above.” RX-0670. For example, Apple relies on the annular rings (22, 22a) shown in FIG. 3 of Cramer (below) as alleged protrusions:



CDX-0012C.025 (showing RX-0670, FIG. 3). Cramer describes these “annular rings extending *above*” the case of the watch. RX-0670 at 9:51-56.

Apple’s patents and validity positions confirm the terms “arranged over”/“positioned over”/“above” refer to covering the interior surface or aligning with the photodiodes, regardless of the device’s orientation when in use. See *W.L. Gore & Assoc, Inc. v. Garlock, Inc.*, 842 F.2d

[REDACTED]

1275, 1279 (Fed. Cir. 1988) (claims must be interpreted the same way for infringement and validity).

2. “Openings”/“Through Holes”

The six Asserted Claims each recite “openings”/“through holes”:

- “a plurality of *openings* extending through the protrusion and positioned over the three photodiodes” (’501 [1D]);
- “a protrusion comprising a convex surface including separate *openings* extending through the protrusion and lined with opaque material, each *opening* positioned over a different one of the four photodiodes” (’502 [19C]);
- “a plurality of *openings* in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each *opening* defined by an opaque surface configured to reduce light piping” (’502 [28F]);
- “a plurality of *openings* provided through the protrusion and the convex surface, the *openings* aligned with the photodiodes” (’648 [8E]);
- “a plurality of *through holes*, each *through hole* including a window and arranged over a different one of the at least four photodiodes” (’648 [20D]).

The openings or through holes allow light to reach the detector. For example, ’501 [1E] recites “the plurality of openings configured to allow light to reach the photodiodes.” The other Multi-Detector Patent Claims recite similar features for light from the measurement site to pass through “openings”/“through holes” before reaching the detector:

- “four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user” (’502 [19B]);

b. Ground 2 – Lumidigm + Seiko 131 + Cramer Does Not Render Obvious Any Asserted Claim

Apple argues the combination of Lumidigm with Seiko 131 and Cramer renders obvious the Asserted Claims of the Multi-Detector Patents. Apple’s purported combination of Lumidigm with Seiko 131 and Cramer—both considered by the Patent Office—fails to render any claim obvious for each of the additional reasons below.

i. Cramer Does Not Disclose or Suggest the Claim Elements For Which It Is Asserted

As summarized in Madisetti’s demonstrative (CDX-0012C.025) and explained in this section, Cramer (RX-0670) does not disclose or suggest the claim elements for which it is asserted.

Cramer Does Not Disclose or Suggest At Least the Following Claim Features/Elements

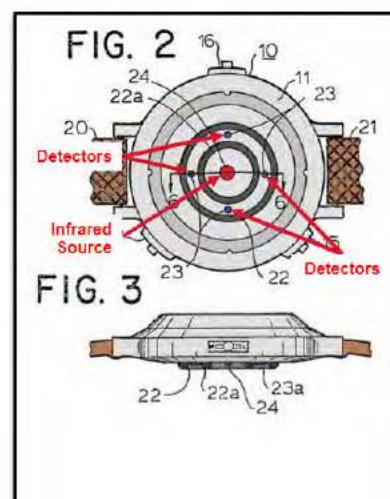
✖ **NO** protrusion arranged over or above the interior surface or photodiodes

• FIGS. 2-3 Embodiment: Bosses 22, 22a are discrete annular rings

✖ **NO** protrusion comprising convex surface

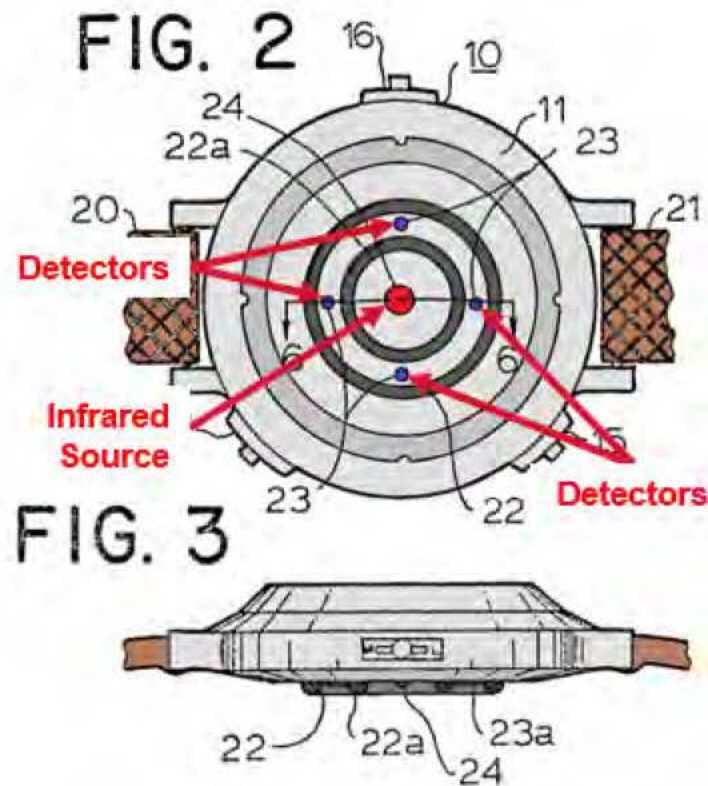
✖ **NO** openings or windows in openings in protrusion as claimed

✖ **NO** protrusion comprising opaque surface/material or chamfered edge



CDX-0012C.025. Warren relied on Cramer FIGS. 2-3, 6. RDX-8.67-68; Tr. (Warren) at 1231:15-22, 1232:21-1233:14. But nothing in Cramer teaches the claimed protrusion.

First, Cramer does not disclose or suggest a protrusion arranged over or above the interior surface or photodiodes, which applies to '501 [1C], '502 [19C] and [28E], and '648 [20C]. The alleged protrusion or protrusions (shown below in dark gray) are bosses 22, 22a:

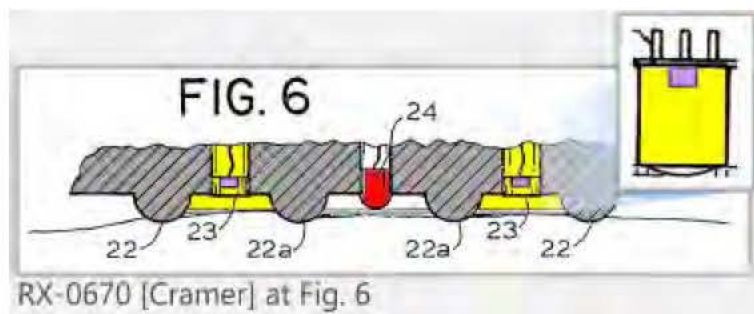


CDX-0012C.025. The bosses are discrete annular rings around a portion of a flat surface. RX-0670 at FIGS. 2-3, FIG. 6, 9:51-56. Madisetti confirmed that in “FIGS. 2 and 3, the bosses 22 and 22a, are just annular rings. They are not the claimed protrusion with its properties.” Tr. (Madisetti) at 1335:15-17; *id.* at 1334:23-1335:2. Neither Cramer boss (22, 22a) is arranged over or above the detectors (23) or an interior surface on which the detectors are arranged. RX-0670 at FIGS. 2-3. Madisetti confirmed “there’s no protrusion arranged over or above the interior surface or the photodiodes.” Tr. (Madisetti) at 1335:3-7. He also explained that the alleged protrusion, is not the claimed protrusion because “it’s not over these photodiodes” (23) or the interior surface. *Id.* at 1335:8-10.

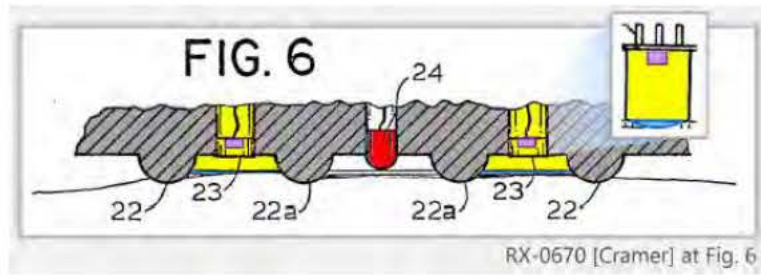
Second, Cramer does not disclose or suggest “openings”/“through holes” in a protrusion comprising a convex surface that are “over”/“above”/“aligned with” the photodiodes or “windows”/“optically transparent material” in the protrusion openings. This shortcoming applies

to every asserted claim, including the following elements: '501 [1D], '502 [19C]-[19D], [28F]-[28G], '648 [8E]-[8F], [20D]. Apple argues a POSITA would understand Cramer's reference to a "CLT 2160 photodiode" to infer its detectors 23 would have an associated opening and window. Tr. (Warren) at 1231:23-1232:9; RDX-0008.65, RDX-0008.70, RDX-0008.73-74. However, those photodiodes are located in the flat space between the annular rings or bosses 22, 22a—not in or "through" a "protrusion comprising a convex surface" as every claim requires. Thus, Cramer does not disclose or suggest "openings or windows in the openings in the protrusion as claimed." Tr. (Madisetti) at 1335:22-25.

Warren's demonstratives show that the alleged "openings"/"through holes" (in yellow below) are *between* the discrete bosses 22 and 22a rather than in or extending through "a protrusion comprising a convex surface" as claimed:



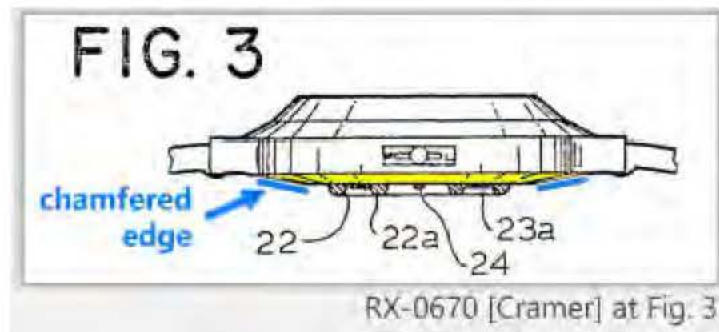
RDX-0008.70. Because Cramer does not disclose or suggest the claimed openings, it does not disclose or suggest the claimed windows therein. The alleged windows of Cramer (in blue below), like the alleged openings (yellow), are located *between* discrete bosses (22, 22a) rather than included in openings in "a protrusion comprising a convex surface" as claimed.



RDX-0008.65.

Third, because Cramer does not disclose or render obvious a protrusion comprising a convex surface, it cannot disclose or render obvious the claimed protrusion or protrusion openings further comprising an opaque lateral surface or opaque material configured to avoid or reduce light piping, which is required by '501 [1E], '502 [28F], and '648 [24].

Fourth, Cramer does not disclose or suggest “the protrusion further comprising one or more chamfered edges” of '648 Patent Claim 30. Tr. (Madisetti) at 1336:1-4. Apple relies on the bosses (22, 22a) of FIGS. 2-3, 6 as protrusions. RDX-0008.67-68; Tr. (Warren) at 1231:15-22, 1232:21-1233:14. Cramer does not disclose or suggest “the protrusion further comprising one or more chamfered edges” for each of the above-described reasons that it does not disclose or suggest a protrusion as claimed. Further, the claim requires the protrusion comprise one or more chamfered edges, but the alleged protrusion or protrusions in FIGS. 2-3 (bosses 22, 22a) *do not* comprise the chamfered edge (blue) identified by Warren below.



RDX-0008.75. Rather, as shown above, Warren ignored the claim language to identify an irrelevant surface in Cramer.

ii. **Seiko 131 Does Not Disclose or Suggest the Claim Elements For Which It Is Asserted**

As summarized in Madisetti's demonstrative CDX-0012C.023 and explained in this section, Seiko 131 (RX-0666) does not disclose or suggest the claim elements for which it is asserted.

Seiko 131 Does Not Disclose or Suggest At Least the Following Claim Features/Elements

-
- ✗ **NO** protrusion comprising a convex surface with openings '501 [1D], '502 [19C], [28F], '648 [8E], [20D]
 - One phototransistor 32 in FIG. 28 embodiment
 - ✗ **NO** opaque lateral surface/material configured to avoid or reduce light piping '501 [1D], '502 [19C], '648 [8E]
 - Alleged protrusion 341A = transparent glass. RX-666 at 10:30-33, 10:36-41.
 - ✗ **NO** windows in openings in protrusion '502 [19C], [28F], '648 [8E], [20D]
 - ✗ **NO** protrusion comprising one or more chamfered edges '648 [8E]

CDX-0012C.023.

First, Seiko 131 does not disclose or suggest a protrusion comprising a convex surface with “openings”/“through holes” in or through the protrusion that are “over”/“above”/“aligned with” the photodiodes. This failure applies to every Asserted Claim, including claim elements '501 [1D], '502 [19C] and [28F], and '648 [8E] and [20D]. Apple asserts the “outside surface” 341A of the “light transmittance plate” 34A in FIG. 28 of the Seiko 131 finger sensor is a protrusion as claimed, and that light transmittance plate 34A teach the claimed openings. RDX-0008.73; Tr. (Warren) at 1233:15-22.

[REDACTED]

The specification teaches multiple ways to reduce or avoid light piping. It describes using a hard opaque plastic material for the protrusion, which reduces light piping. JX-0001 at 7:65-8:7. It also discloses adding height to the protrusion “assists in deflecting light piped through the sensor.” *See, e.g., id.* at 25:47-62, 7:65-8:7. The added height allows light to pass through the walls *around* the sensor rather than being directed toward the detectors. *Id.* at 25:47-59. The specification also discloses noise shields “constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.” *Id.* at 43:32-36. Madisetti explained that these disclosures teach how to reduce or avoid light piping. Tr. (Madisetti) at 1350:4-21, 1352:25-1353:11; CDX-0012C.046. Indeed, Warren acknowledged that the specification describes light piping, and hard opaque plastics that reduce or avoid it. Tr. (Warren) at 1247:24-1248:4.

A POSITA would have understood that light piping could be reduced or avoided using the above-described solutions in the specification.

F. Enforceability (Prosecution Laches)

To establish laches, Apple bore the burden of establishing “unreasonable and unexplained delay in prosecution” and prejudice. *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728-29 (Fed. Cir. 2010). Prosecution laches “may render a patent unenforceable” when unreasonable and unexplained delay “constitutes an egregious misuse of the statutory patent system” *Id.* at 728. The Federal Circuit has approved of prosecution laches only three times—each time involving decades-long delays not at issue here, in prosecution of pre-GATT patents. *See Hyatt v. Hirshfeld*, 998 F.3d 1347, 1361, 1372 (Fed. Cir. 2021). Apple did not even attempt to meet its burden to show prosecution laches, especially for these post-GATT applications.

[REDACTED]

First, Apple established no unreasonable and unexplained delay. All testimony was to the contrary. Apple's sole witness, Masimo's patent lawyer, Scott Cromar, testified there was no delay during the alleged 12-year period touted by Apple in its opening statement. Tr. (Cromar) at 1036:19-21 (discussing prosecution from 2008-2012). To the contrary, there were "over 30 applications or continuations filed and actively prosecuted" *Id.* at 1036:6-18. Cromar also testified there were "a dozen applications being actively prosecuted" during the alleged five year "gap" relied on by Apple. *Id.* at 1039:7-12 (discussing prosecution from 2010-2015). Cromar explained that Apple's opening slide on laches omitted many of these filings, such that Apple's slide was a "misrepresentation." *Id.* at 1038:10-19.

Masimo also presented unrebutted expert testimony from Robert Stoll, the former USPTO Commissioner for Patents, who is an "expert on Patent Office practice and procedure." *Id.* at 1409:9-1410:5. Stoll opined there was a "continuous unbroken chain of patent prosecution. There was no delay." Tr. (Stoll) at 1415:2-10; *see also* CX-1621, CX-1622, CX-1623 (prosecution histories). Stoll outlined the various ways a patentee might delay prosecution and found "*none* of those actions that occurred." *Id.* at 1413:10-25. Apple did not cross-examine Stoll on any of his testimony.

Second, Apple identified no prejudice arising from any unreasonable or unexplained delay. Apple presented no witnesses on this issue and no evidence it would have changed course if Masimo had prosecuted its patents differently. Stoll explained that the specification was published and available to the public on February 4, 2010. *Id.* at 1412:7-16; CX-0137.

Rather than prove any actual element of laches, Apple attempted to show that Masimo's patent filings followed the releases of Apple's watches. Tr. at 52:12-24. In its opening statement, Apple promised to show the timing of Masimo's filings was "not a coincidence at

[REDACTED]

all.” *Id.* at 22-24. Cromar rejected any such “correlation,” testifying, “I don’t think so, especially because a huge portion of the prosecution happened before any Apple Watch was released.” Tr. (Cromar) at 1040:1-9. Cromar also explained that other events occurred, such as Apple producing prior art through IPRs and the district court case and Masimo’s development of its watch. *Id.* at 1034:11-1035:19. Regardless, even if Apple could show such a correlation, there is nothing improper or inequitable about drafting claims to cover a competitor’s product. *See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988). Because Apple’s laches defense fails, it has not established unclean hands either.

IV. ’745 PATENT

Apple infringes ’745 Patent Claims 9 and 27. The 745 DI Products practice Claim 18.

A. Level of Ordinary Skill in the Art

The parties stipulated to the same level of ordinary skill as the Multi-Detector Patents. Doc. ID. 770692 ¶10; Tr. (Madisetti) at 1328:15-1329:2; Tr. (Sarrafzadeh) at 1089:1-15; CDX-0012C.004; RDX-0007.81C.

B. Claim Construction

1. “second shape”

The parties briefed one term, “second shape,” from Claims 1 and 20. The currently proposed constructions for “second shape” are:

Masimo’s Proposed Construction	Apple’s Proposed Construction
A shape that is different from the first shape, where a difference in size, without any other difference, is not a shape different from the first shape”	Plain and ordinary meaning (<i>i.e.</i> , a shape different than the first shape).

Apple clarified after the Markman hearing that “both sides agree that a mere difference in size is neither necessary nor sufficient to change a first shape into a ‘second shape.’” Doc. ID

VI. DOMESTIC INDUSTRY – ECONOMIC PRONG

For the Masimo Watch and for the rainbow® sensors, an industry in the United States exists and is in the process of being further established, under both sub-prongs (A) and (B). That was true as of the Complaint and as of the Evidentiary Hearing. Masimo far exceeds the “relatively low” threshold for satisfying the economic prong. *See Certain Elec. Devices*, Inv. No. 337-TA-701, Order No. 58, 2010 WL 5621540, at *4 (Nov. 18, 2010); *Certain Battery-Powered Ride-On Toy Vehicles*, Inv. No. 337-TA-314, USITC Pub. No. 2420, I.D. at 21 (Aug. 1991) (“The purpose of the domestic industry requirement is to prevent the ITC from becoming a forum for resolving disputes brought by foreign complainants whose only connection with the United States is ownership of a U.S. patent.”).

Masimo conducted all of its research and development for the Masimo Watch, including its underlying wrist-worn parameter-monitoring technology, in Irvine, California. Tr. (Kiani) at 118:24-119:12. [REDACTED]

[REDACTED]



CX-0835C at 105; Tr. (Scruggs) at 434:18-21; CX-0635C. [REDACTED]

[REDACTED] CDX-0015C.007-008; CX-0648C;

Tr. (Young) at 504:9-25; Tr. (McGavock) at 535:24-537:21.

Apple repeats its unsuccessful MIL #1, arguing that the economic prong analysis should be limited to pre-Complaint activities. Apple is incorrect. But even if the analysis were so restricted, Masimo would still satisfy the domestic industry requirement. As of the Complaint, Masimo had spent [REDACTED] domestically to develop and build the Watch, and employed [REDACTED] employees domestically to do so. CDX-0015C-007; CX-0648C (summarizing CX-0623C, CX-0624C, CX-0629C, CX-0632C, CX-0634C, CX-0635C, CX-0636C, CX-0646C, CX-0647C, CX-0618C, CX-0620C).

Moreover, Masimo's post-Complaint domestic industry satisfies Apple's significant and unusual development standard. The Commission has confirmed that domestic manufacturing is an "extraordinary" and "significant and unusual" development warranting the inclusion of post-

[REDACTED]

CDX-0015C.014 (summarizing CX-0629C; CX-0634C; CX-0635C; CX-0636C; CX-0640C; CX-0641C; CX-0644C; CX-0646C; CX-0647C; CX-0649C).

Masimo addresses the significance of its domestic expenditures regarding the rainbow® Sensors in the subsequent section within the heading for labor or capital.

B. Significant Employment of Labor or Capital

1. Masimo Watch

Masimo has employed [REDACTED] in eligible domestic labor or capital specifically for the Masimo Watch, [REDACTED] in labor or capital for R&D on [REDACTED]

[REDACTED]

[REDACTED]

Masimo's domestic employment of labor or capital for the Masimo Watch between 2019 Q3 and 2021 Q1 have included (*see* CDX-0006C.004):

- [REDACTED]
[REDACTED] (CX-0629C at [REDACTED]
[REDACTED] tab; Tr. (Young) at 489:2-21);
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (Tr.
(Young) at 489; CX-0635C at R&D Summary tab; CDX-0006C.008 (summarizing CX-
0635C at [REDACTED] tabs));
- [REDACTED]
[REDACTED] (Tr. (Young) at

[REDACTED]
[REDACTED]
490:19-492:13; CX-0635C at [REDACTED]; CDX-0006C.010 (excerpting CX-0635C; CX-0611C; CX-0835C at 41);

- [REDACTED] (Tr. (Young) at 492:11:15; CX-0635C at [REDACTED]);
- [REDACTED]
[REDACTED]
[REDACTED] (Tr. (Young) at 492:16-493:7; CX-0635C at [REDACTED]
[REDACTED]);
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (Tr. (Young) at 493:8-494:17; CX-0624C [REDACTED]
- [REDACTED] (Tr. (Young) at 494:18-22; CX-0623C at “Summary” tab);
- [REDACTED]
(Tr. (Young) at 494:23-495:2; CX-0646C at “Summary” tab);
- [REDACTED] (Tr. (Young) at 495:3-10; CX-0632C at “Summary” tab);
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (CX-0618C at 4 and 5), and [REDACTED]

[REDACTED] (CX-0620C at 14) (Tr. (Young) at 495:11-496:19).

Masimo's domestic expenditures in the categories immediately above for the Masimo Watch total [REDACTED]

Moreover, the development of the Masimo Watch relied on [REDACTED]
[REDACTED]
Tr. (McGavock) at 560:6-561:1. Masimo has estimated that [REDACTED] in total U.S.-based R&D in that timeframe has been devoted to wrist-worn technology—ranging between [REDACTED] annually. CX-0640C at “Summary” tab; Tr. (Young) at 497:1-20.

Even pursuant to Thomas' opinion excluding Masimo's wrist-worn expenditures, post-complaint expenditures, and expenditures from before 2019, that would still leave [REDACTED] in labor or capital that Masimo has spent on qualified domestic activities for the Masimo Watch. (CDX-0015C.010 (summarizing CX-0618C, CX-0620C, CX-0623C, CX-0624C, CX-0629C, CX-0632C, CX-0634C, CX-0635C, CX-0636C, CX-0646C, CX-0647C); Tr. (McGavock) at 541:22-543:2.

Masimo [REDACTED]
[REDACTED] (see CDX-0006C.0030-31; Tr. (Young) at 500:23-502:1):

- [REDACTED] (CX-0635C at R&D Summary tab);
- [REDACTED] (CX-0635C at “R&D Summary” tab, “Capital items” row);

- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]

Masimo's projected domestic expenditures in the categories immediately above for the Masimo Watch total [REDACTED] in addition to the pre-Complaint expenditures.

[REDACTED]

The significance of Masimo's employment of labor for Masimo Watch is also shown by headcount. For example, in Q1 2021, Masimo employed [REDACTED] full-time for R&D on Masimo Watch based on allocating [REDACTED] time spent on the project. CX-0648C; Tr. (Young) at 503:20-504:8. Masimo employed [REDACTED] full-time employees based on an allocation of [REDACTED] employees across all roles as of Q1 2021 for this project. CX-0648C; Tr. (Young) at 504:9-13. When Masimo's F&PA team prepared its financial spreadsheets, [REDACTED]

[REDACTED] CX-0648C; Tr. (Young) at 504:14-18. [REDACTED]

[REDACTED]

[REDACTED] *Id.* at 504:19-22.

Several metrics confirm the significance of Masimo's domestic activities and expenditures for the Masimo Watch. [REDACTED]

[REDACTED] Tr. (Kiani) at 121:11-123:16; Tr. (McGavock) at 543:16-544:14. [REDACTED]

[REDACTED] Tr. (Kiani) at 126:19-23. [REDACTED]

[REDACTED]

[REDACTED] Tr. (Scruggs) at 433:13-15; Tr. (McGavock) at 543:16-544:14.

Masimo's domestic activities for the Masimo Watch are also quantitatively significant. Masimo [REDACTED]. Tr. (Kiani) at 321:23-322:5. [REDACTED]. Tr. (McGavock) at 544:21-545:25; CX-0629C [REDACTED]

[REDACTED] Tr. (McGavock) at 544:21-545:25; CX-

0629C (“ [REDACTED] ” tab). [REDACTED]

[REDACTED]

Tr. (McGavock) at 544:21-545:25; CDX-0015C.012 (summarizing CX-0635C). Moreover, Masimo undertook [REDACTED]

[REDACTED] as part of developing the Masimo Watch. Tr. (Al-Ali) at 323:18-324:25; Tr. (Mushin) at 344:14-345:1. Masimo [REDACTED]

[REDACTED]. Tr. (McGavock) at 545:3-17; CDX-0015C.012 (summarizing CX-0635C “Employee Report” tab, [REDACTED] The importance of [REDACTED]

[REDACTED] further confirms the significance of Masimo’s domestic activities for the Watch. *See Certain Handheld Electronic Computing Devices*, Inv. No. 337-TA-769, Doc. ID 472348, Order No. 34 at 7-12 (Feb. 6, 2012) (value added by domestic activities supports economic prong.) [REDACTED]

[REDACTED] CX-0612C at 8 and 57.

In April 2022, Masimo completed its acquisition of Sound United for \$1.025B, which Masimo [REDACTED]

CX-1637 at 19-20; Tr. (Young) at 483:1-18. The Masimo Watch’s significance to Masimo is further confirmed by Masimo including it as the second product addressed in its 2021 Earnings Presentation, and identifying it as part of Masimo’s strategic expansion into consumer health and wellness. CX-1637 at 17 and 21; Tr. (Young) at 482:14-25; *see also* CX-0612C.

Masimo’s expenditures are also significant in absolute terms, without requiring comparative analysis. Apple never suggests that amounts exceeding [REDACTED] in Masimo Watch-specific R&D labor expenditures is quantitatively insignificant. Neither can Apple identify any support that the [REDACTED] in pre-Complaint expenditures, which remain after addressing Apple’s

criticisms, is somehow insignificant. Indeed, Apple's expert Thomas, criticized Masimo's calculations and evidence, but never opined that the amounts are insignificant. Tr. (Thomas) at 1322:6-1323:7.

2. rainbow® Sensors

In addition to conducting R&D and manufacturing activities at [REDACTED] facilities discussed for Masimo Watch, Masimo also manufactures sensors for the rainbow® sensors at its facility in [REDACTED]. Tr. (McGavock) at 566:18-567:3.

Masimo's domestic employment of labor or capital for the rainbow® sensors have included, and are projected to include (*see* CDX-0015C.016; CX-0644C; CX-0632C; CX-0627C):

- [REDACTED]
[REDACTED] from Q2 2021-2023 calculated by allocating employee cost according to time dedicated by the employees to the rainbow® sensors (CX-0644C; CX-0627C);
- [REDACTED] from 2018-Q1 2021, and projected [REDACTED] from Q2 2021-2023 calculated by allocating employee cost according to time dedicated by the employees to the rainbow® sensors (CX-0633C at "R&D Spend History" tab; CX-0644C);
- Cost-of-goods-sold domestic expenditures of [REDACTED] from 2018-Q1 2021, and [REDACTED] (CX-0638C);
- [REDACTED]
[REDACTED] (CX-0641C);

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

**In the Matter of
CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S SECOND CORRECTED POST-HEARING BRIEF

Id. 1198:17-1999:6; RDX-8.90 (summarizing Tr. [Warren] 1198:16-1200:15, RX-0510, RX-0648); *see also* incorporated exhibits.

b. Anticipation Under 35 U.S.C. § 102(a) / Single-Reference Obviousness Under 35 U.S.C. § 103(a) Based on Lumidigm

As discussed below and confirmed at trial by Professor Warren, Lumidigm anticipates all asserted claims of the Poeze Patents, and at a minimum, renders all asserted claims obvious. Tr. [Warren] 1207:1-12.²⁰

(1) Lumidigm

U.S. Patent No. 7,620,212, titled “Electro-Optical Sensor” and originally assigned to Lumidigm, has an August 13, 2002 priority date and is prior art to the Poeze Patents under 35 U.S.C. § 102. RX-0411 (“Lumidigm”). The lead inventor, Dr. Robert Rowe, previously worked for Rio Grande Medical Technologies on light-based sensors that measured glucose and other blood analytes. Tr. [Rowe] 1142:10-17, 1143:12-1144:8, 1146:18-1147:9. Lumidigm formed as a spinoff to develop products that would use the same light-based sensors for biometrics. *Id.* at 1142:18-1143:1, 1144:15-1145:3.

Lumidigm’s specification provides “a collation of what was known about [at] the time of optical sensor heads that were used for reflectance mode for spectrometry purposes.” Tr. [Warren] 1204:8-17. Lumidigm’s purported novelty focuses on detecting the liveness of tissue, but

²⁰ Complainants’ expert Dr. Madisetti disagrees that the asserted Poeze Patent claims are invalid. *See* Tr. [Madisetti] at 1385:25-1387:25. Apple requests that the ALJ take judicial notice of the Final Written Decisions and corresponding declarations from Dr. Madisetti (attached hereto as Exs. 1-16). *See Certain Infotainment Sys., Components Thereof, & Automobiles Containing the Same*, Inv. No. 337-TA-1119, 2019 WL 4744857, at *1 (Sept. 23, 2019) (“Judicial notice is appropriate for USPTO decisions related to an asserted patent.”); *Certain Movable Barrier Operator Sys. & Components Thereof*, Inv. No. 337-TA-1118, 2019 WL 1773475 at *1 (Apr. 16, 2019) (same).

Lumidigm repeatedly teaches that the same light-based sensors could be used to measure traditional parameters such as glucose, hemoglobin, and blood oxygenation. RX-0411 at 4:25-29, 10:11-21, 19:16-28; Tr. [Warren] 1204:8-17, 1205:1-11, 1215:18-1216:9; Tr. [Rowe] 1147:10-1148:4.

Lumidigm explains that its sensor can include any number and arrangement of *light sources*, including LEDs, in any of a variety of wavelengths. RX-0411 at 6:38-53, 8:33-9:11, 9:26-34. Lumidigm further confirms that the sensor can include any number and any arrangement of *detectors*, including “a single element, a plurality of discrete elements, or a one-or-two dimensional array of elements.” *Id.* at 6:54-63, 9:39-45, 9:52-57. Lumidigm illustrates examples of such arrangements in Figures 3 through 7B, noting that “other numbers and arrangements” of sources and detectors “may alternatively be used” and that “[m]any variants exist:

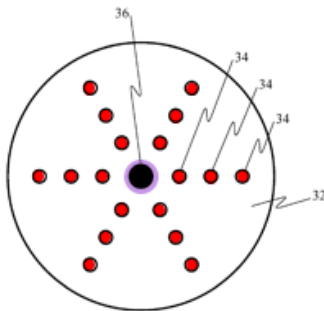


FIG. 3

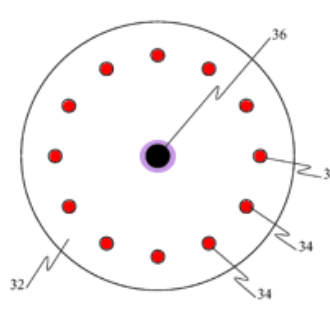


FIG. 4

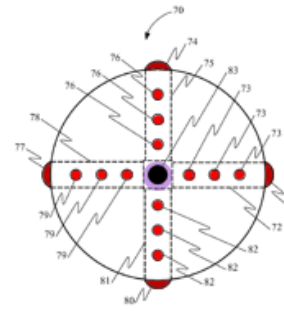


FIG. 5

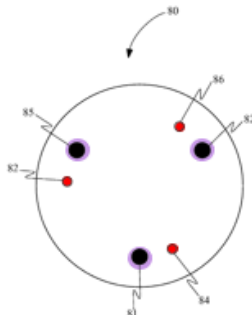


FIG. 6

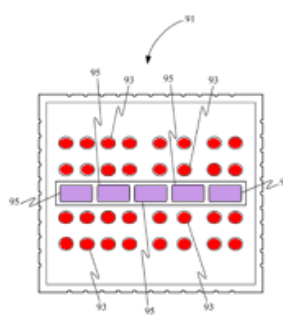


FIG. 7A

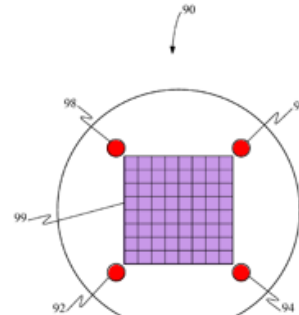


FIG. 7B

RX-0411 at Fig. 3-7B, 9:30-45; Tr. [Warren] 1204:18-12:05:11; Tr. [Rowe] 1148:5-19.²¹

Lumidigm explicitly confirms that the head of its sensor (i.e., the part in contact with the user's tissue) can have a “*compound curvature on the optical surface* to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 at 7:58-63.

Lumidigm also discloses that the sensor can be incorporated into a “portable electronic device” and provides as exemplary devices: key fobs, cell phones, personal digital assistants, and user-worn watches.

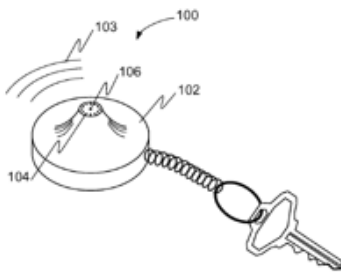


FIG. 8A

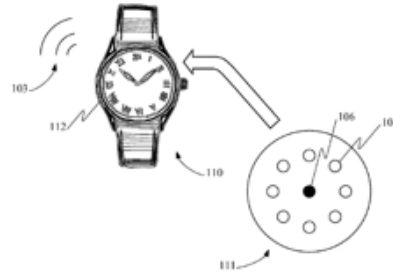


FIG. 8B

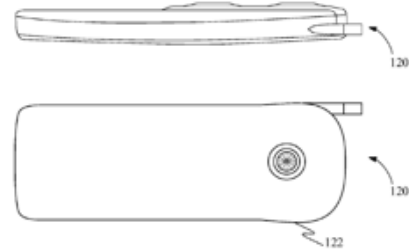


FIG. 8C

RX-0411 at Fig. 8A-C, 3:35-37. Lumidigm further explains that its wristwatch embodiment can include “*any* of the sensor geometries previously disclosed or other equivalent configurations.” *Id.* at 11:60-12:2; Tr. [Warren] 1205:12-1206:7; Tr. [Rowe] 1152:4-25.

Lumidigm's wristwatch and other portable devices also include a number of other standard components, including internal processors and memory for calculating and storing measurements (e.g., RX-0411 at Fig. 9, 12:56-13:14) and interfaces for wireless communications (e.g., *id.* at Figs. 8D-8E, 13:9-12).

²¹ Apple has added color to Lumidigm's figures throughout this brief, to highlight the relevant components.

(2) '501 Patent, Claim 12

Lumidigm discloses all limitations of '501 claim 12 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1207:1-1215:10.

(a) '501 Patent, Claim 1

Limitation [1Preamble]: Lumidigm discloses “[a] user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising.”

Lumidigm discloses that its sensor can be incorporated into a variety of devices including a user-worn wristwatch, as shown in Figure 8B:

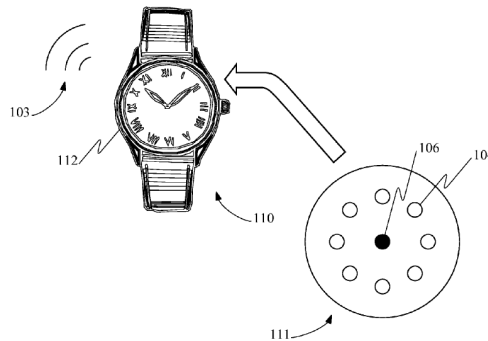


FIG. 8B

RX-0411 at 11:60-12:2, Fig. 8B; Tr. [Warren] 1207:23-1208:13; RDX-8.23 (summarizing RX-0411).

Lumidigm explains that, in this embodiment, the “biometric reader 11 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin on the area of the wrist.” RX-0411 at 11:61-64. Lumidigm’s sensor uses those signals to measure physiological parameters, based on the “concentration of a substance in the individual’s tissue,” including “oxygenation and/or hemoglobin levels in the blood.” *Id.* at 19:16-28, *see also* 11:61-64; Tr. [Warren] 1208:1-13, 1214:12-1215:4.

Lumidigm introduces its wristwatch embodiment after discussing numerous illustrative arrangements for the sensor’s light sources, detectors, and sensor head, and confirms that “any of

the sensor geometries previously disclosed or other equivalent configurations” can be used in the wristwatch embodiment. RX-0411 at 11:60-12:2. A POSITA²² would have understood that this would include any of the disclosed arrangements of LEDs and photodiodes, any of the disclosed geometries for the sensor head including a “compound curvature,” and any equivalent configurations. Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4.

Limitation [1A]: Lumidigm discloses “*at least three light emitting diodes (LEDs).*”

The concept of using multiple LEDs in a sensor has been “known for many decades.” Tr. [Warren] 1208:14-23, *see also* 1189:25-1191:22, 1195:6-12. Lumidigm teaches that its sensor can include any type of light sources, including LEDs, in any variety of wavelengths. RX-0411 at 6:38-53. For example, each light source in a sensor can comprise “sets of LEDs, laser diodes VCSELs, or other solid-state optoelectronic device,” and the light sources can have the same wavelength characteristics, differing wavelength characteristics, or some sources with the same wavelengths and others with different wavelengths. *Id.* at 6:43-53; Tr. [Warren] 1208:14-23. Lumidigm also discloses that the sensor can include any number of light sources, in any arrangement.

Lumidigm includes a series of illustrative examples in Figures 2 through 7B, including examples with three or more LEDs, and confirms that “other arrangements” also can be used. RX-0411 at 9:26-34, Figs. 2-7B. For example, Figure 6 teaches that the sensor can have *three LEDs* positioned relative to three photodiodes:

²² Professor Warren confirmed that he applied the parties’ agreed definition of a person of ordinary skill in the art in evaluating anticipation and obviousness. Tr. [Warren] 1207:1-22. All references to a “POSITA” in this brief, for purposes of the Poeze Patents, are from the perspective of a POSITA with this skill level, as of the priority date of the Poeze Patents.

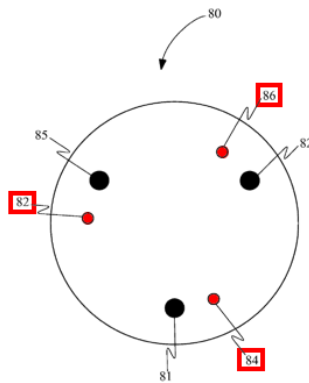


FIG. 6

RX-0411 at Fig. 6, 9:15-18, *see also* Figs. 3-5 and 7A-7B; Tr. [Warren] 1208:14-23; RDX-8.24 (summarizing RX-0411).

As referenced above, Lumidigm also discloses that any of the disclosed LED arrangements can be used in the wristwatch embodiment. RX-0411 at 11:60-12:2; Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4.

Limitation [1B]: Lumidigm discloses “*at least three photodiodes.*”

The concept of using three or more photodiodes in a sensor also was “quite well known,” dating back more than 40 years. Tr. [Warren] 1208:25-1209:17, *see also* 1191:23-1192:22, 1195:13-15. Lumidigm discloses that its sensor’s detectors “may comprise a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements,” in essentially any arrangement. RX-0411 at 6:54-56. Lumidigm further explains that the detectors can be made of various materials, including “InGaAs,” and that “a suitable detector material is silicon.” *Id.* at 6:56-63; *see also* Tr. [Warren] 1208:25-1209:17. A POSITA would have understood that a detector made of InGaAs or silicon would be a photodiode. *Id.* at 1209:14-17 (“no doubt” a POSITA would understand these as photodiodes).

Lumidigm provides several illustrative examples, including examples with “at least three photodiodes” and again confirms that “other numbers and arrangements” may “alternatively be used.” *Id.* at 9:30-34. For example, Figure 6 shows an example with *three photodiodes*:

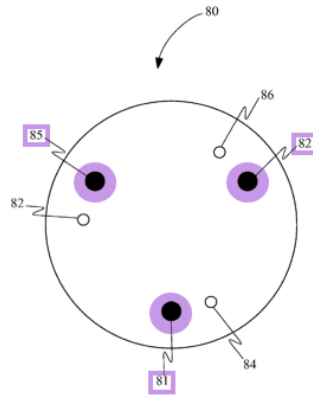


FIG. 6

RX-0411 at Fig. 6, *see also* Figs. 7A-7B; Tr. [Warren] 1208:25-1209:17; RDX-8.25 (summarizing RX-0411).

As referenced above, Lumidigm confirms that any of the disclosed photodiode arrangements can be used in its wristwatch embodiment. RX-0411 at 11:60-12:2; Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4.

Lumidigm also discloses that the three photodiodes are “*arranged on an interior surface of the user-worn device.*” For example, Figure 2, a cross-section of Figure 1, shows a detector placed on an interior surface of the device:

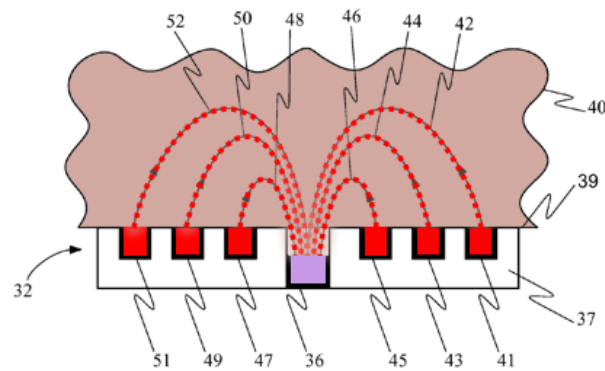


FIG. 2

RX-0411 at Fig. 2, 7:5-6, 8:1-4; Tr. [Warren] 1209:19-1210:11; RDX-8.26 (summarizing RX-0411). Although Figures 1 and 2 include only one detector, item 36, Lumidigm states that detector 36 is representative and “may comprise . . . a plurality of discrete elements.” RX-0411 at 6:54-56, *see also* 3:9-11. A POSITA would have understood that, for the embodiments with multiple detectors, such as Figure 6, the additional detectors would be similarly arranged on the interior surface below the sensor head. Tr. [Warren] 1209:19-1210:11.

Lumidigm also discloses that the three photodiodes are “*configured to receive light attenuated by tissue of the user.*” This was “another well-known principle,” and is illustrated in Figure 2, showing the photodiodes receiving light that has been “reflect[ed] back” to the photodiodes after it has “propagated through the tissue.” Tr. [Warren] 1209:19-1210:11. Lumidigm explains that the detectors are “disposed relative to the light sources to detect light that has propagated through tissue” and that the resulting signals “contain[] information about the tissue optical properties.” RX-0411 at 3:25-28, 7:26-29, Fig. 2; Tr. [Warren] 1209:19-1210:11.

Limitation [1C]: Lumidigm discloses “a *protrusion arranged over the interior surface, the protrusion comprising a convex surface.*”

The concept of using a protrusion with a convex surface was also a “well-known idea,” dating back to the “early ‘70s.” Tr. [Warren] 1210:13-1211:8, 1194:17-1195:5, 1195:20-22. As

referenced above, Figure 2 depicts a cross-sectional view of the sensor head, showing detectors recessed and placed on an interior surface below the sensor surface. RX-0411 at 7:5-6, 8:1-4. Although Figure 2 shows a flat sensor head, Lumidigm explains that “[t]he sensor head 32 may also have a *compound curvature on the optical surface* to match the profile of a device in which it is mounted, *to incorporate ergonomic features that allow for good optical and mechanical coupling* with the tissue being measured, or for other technical or stylistic reasons.” *Id.* at 7:57-63, 8:27-28 (“Optionally, the surface of the light relay can be contoured to fit specific product applications and ergonomic requirements.”); RDX-8.27 (summarizing same).

A POSITA would have understood that, when the sensor has a “compound curvature on the optical surface” (i.e., the surface directly in contact with the user’s tissue), it has a protrusion, with a convex surface, arranged over the interior surface holding the detectors. Tr. [Warren] 1210:12-1211:8. Lumidigm expressly teaches the benefits of a “compound curvature,” including for “good optical and mechanical coupling.” RX-0411 at 7:57-63. A POSITA would have understood the benefits of including a convex protrusion, including to improve signal quality. Tr. [Warren] 1210:12-1211:8.

Limitation [1D]: Lumidigm discloses “a *plurality of openings extending through the protrusion and positioned over the three photodiodes.*”

The concept of including individual openings over each photodiode was another “quite well-known” idea, dating back to the “late 60s,” to allow light to reach the detectors. Tr. [Warren] 1211:10-12:12-3, *see also* 1192:25-1193:6, 1195:16-19. Consistent with this concept, Lumidigm explains that its detectors are “recessed from the sensor surface 39 in optically opaque material” and shows an example of such an opening in Figure 2:

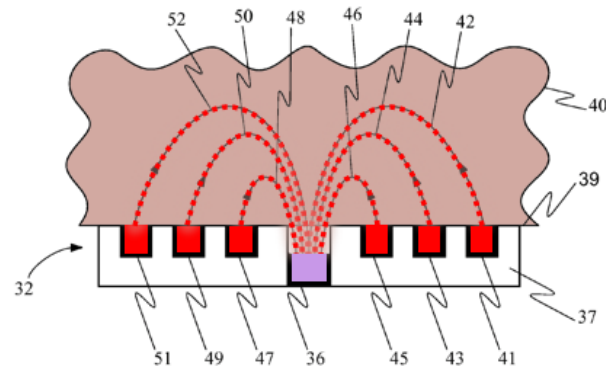


FIG. 2

Again, although Figures 1 and 2 include only one detector, item 36, Lumidigm expressly states that detector 36 is representative and “may comprise . . . a plurality of discrete elements.” RX-0411 at 6:54-56, *see also* 3:9-11. A POSITA would have understood that the sensor can include a plurality of detectors, such as shown in Figure 6, and that for the embodiments with three or more photodiodes, the protrusion would include an opening positioned over each photodiode:

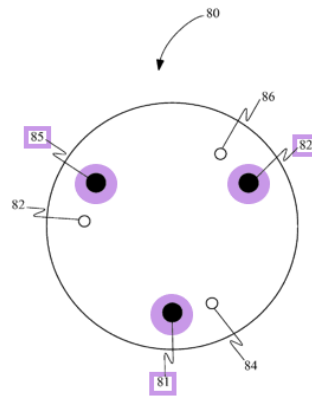


FIG. 6

RX-0411 at Fig. 6, 6:54-56, 3:9-11; Tr. [Warren] 1211:9-1212:10.; RDX-8.28 (summarizing RX-0411).

Limitation [1E]: Lumidigm discloses “*the openings each comprising an opaque lateral surface the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion.*”

The concept of using opaque materials for openings over photodiodes was another “well-known idea,” and also dated back to the “late ‘60s.” Tr. [Warren] 1211:10-1212:3, *see also* 1192:25-1193:6, 1195:16-19. As Professor Warren explained, “if you recess the photodiodes or detectors from the sensor surface in optically opaque material, you can reduce the amount of light that’s detected without going through the tissue.” *Id.* at 1211:10-1212:3. Lumidigm expressly confirms that its detectors 36 are “recessed from the sensor surface 39 in optically opaque material 37” and that this *opaque* material performs “optical blocking” to avoid unwanted light (or light piping) through the protrusion:

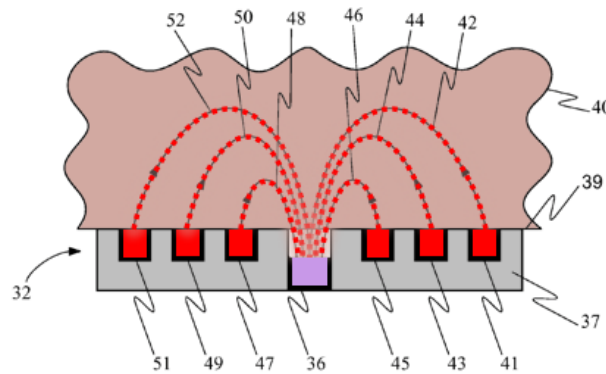


FIG. 2

RX-0411 at Fig. 2, 8:1-11; RDX-8.29 (summarizing RX-0411). A POSITA would have understood that openings made of opaque material over each detector avoid light piping through the protrusion (*i.e.*, light traveling from the LEDs to the photodiodes without first passing through the user’s tissue). Tr. [Warren] 1212:11-1213:3, 1228:16-23. Lumidigm specifically discusses using this configuration to provide “optical blocking” for “shunted” light. RX-0411 at 7:64-8:11. Light shunting is another term for light piping. Tr. [Warren] 1212:22-1213:3.

Limitation [1F]: Lumidigm discloses “*one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.*”

The concept of including a processor to receive signals from photodiodes, calculate measurements, and “manage the overall set of events” is another “well-known idea.” Tr. [Warren] 1213:4-1214:1. Lumidigm discloses that its portable devices, including the user-worn wristwatch, include a “processor [that] is configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor.” RX-0411 at 3:28-31. Lumidigm repeatedly refers to the processors in its devices, and confirms that “[o]nce the light passing through the tissue is detected, the signals can be digitized and recorded by standard techniques,” and the “recorded data can then be processed” into spectral data “as is known to one of ordinary skill in the art.” *Id.* at 9:58-62. This would include receiving and processing signals from the photodiodes and calculating physiological measurements. Tr. [Warren] 1213:4-1214:1; RX-0411 at 19:16-28 (confirming that system “quantif[ies] oxygenation levels”).

Figure 9 provides an example of a “computational device” for “management of the functionality discussed herein” including “processor 332” and “processing acceleration unit 346”:

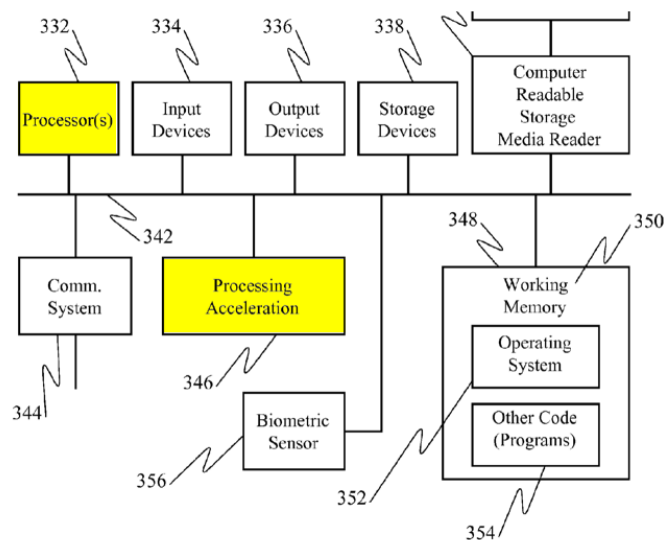


FIG. 9

RX-0411 at Fig. 9, 12:56-67; Tr. [Warren] 1213:4-1214:1; RDX-8.30 (summarizing RX-0411).

Lumidigm further confirms that the components in Figure 9 can be implemented in a “separated

or more integrated manner.” RX-0411 at 12:61-63. A POSITA would have understood that the processors could be implemented in a separate reader or integrated onto the same device as the sensor. Tr. [Warren] 1213:4-1214:1.

(b) '501 Patent, Claim 12

Lumidigm discloses “[t]he user-worn device of claim 1” for the reasons stated above for claim 1.

Lumidigm further discloses “*wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape*.” Lumidigm discloses a “protrusion with a convex surface” for the reasons stated above for '501 limitation [1C]. A POSITA would have recognized that, if a sensor has a protrusion with a convex surface, and that protrusion is positioned next to tissue, “any pressure at all will conform the tissue into a concave shape.” Tr. [Warren] 1214:2-11. Dr. Madisetti confirmed the same understanding. Tr. [Madisetti] 686:1-18.

(3) '502 Patent, Claim 22

Lumidigm discloses all limitations of '502 claim 22 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1215:11-1224:2.

(a) '502 Patent, Claim 19

Limitation [19Preamble]: Lumidigm discloses “[a] *user-worn device configured to non-invasively measure*” a physiological parameter for the reasons discussed above for '501 claim 1, preamble.

Lumidigm further discloses that its user-worn device “*measure[s] an oxygen saturation of a user*.” Lumidigm explains that its devices can be used to perform a variety of functions including measuring the “physiological state of an individual” using “a hemoglobin monitor.” RX-

0411 at 19:16-19. Lumidigm further explains that this functionality detects “spectroscopic changes [that] are correlated with oxygenation and/or hemoglobin levels in the blood” and provides “the ability to quantify oxygenation levels.” *Id.* at 19:22-28; RDX-8.35 (summarizing RX-0411).

A POSITA would have recognized from these disclosures that Lumidigm’s devices are configured to quantify oxygenation levels. Tr. [Warren] 1215:18-1216:9. Moreover, a POSITA “would not have needed any additional information to make [pulse oximetry functionality] work” in Lumidigm’s watch embodiment because this functionality was well understood at the time. *Id.* at 1216:10-25. In fact, Professor Warren and his students were able to build sensors and “work[] with them on their wrists” years earlier. *Id.* Although Apple had significant challenges to overcome in implementing pulse oximetry on Apple Watch, given the limited space and other competing features in Apple Watch, the simple light management problems addressed in the Poeze Patents had already been solved. DocID 773735 (substituting Warren Op. ¶ 244 for Tr. [Warren] 1217:11-21); Tr. [Warren] 1243:5-16.

Limitation [19A]: Lumidigm discloses “*a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs).*”

Lumidigm discloses that its sensor can include any number and arrangement of LEDs, including in its wristwatch embodiment, for the reasons discussed above for ’501 claim 1, limitation [1A]. *E.g.*, RX-0411 at 6:38-53, 11:60-12:2, Fig. 6. Lumidigm further explains that the “light sources” can include “sets of LEDs.” *Id.* at 6:48-53. A POSITA would have understood a “set of LEDs” as a “grouping” of LEDs, each including “for example, three LED dies.” Tr. [Warren] 1190:25-1191:6, 1205:1-11.

The concept of including four or more emitters in an optical sensor, each comprising a set of LEDs, has been known for at least thirty years. Tr. [Warren] 1191:7-22, 1195:10-12. Lumidigm's illustrative examples including multiple examples with four or more sets of LEDs, including Figures 3, 5, 7A and 7B:

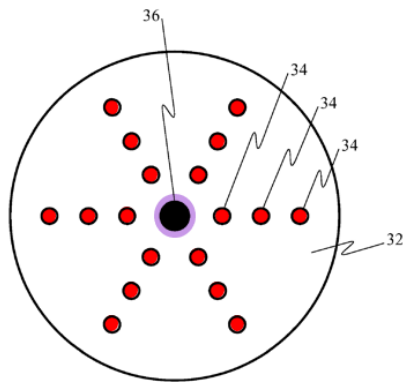


FIG. 3

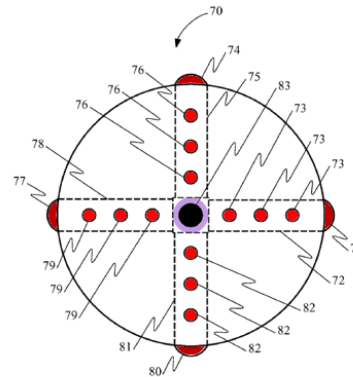


FIG. 5

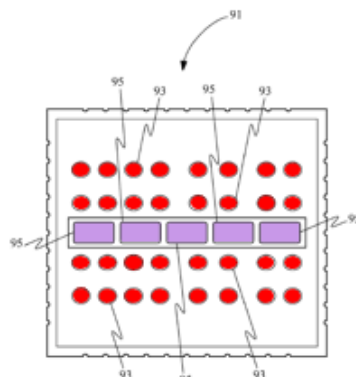


FIG. 7A

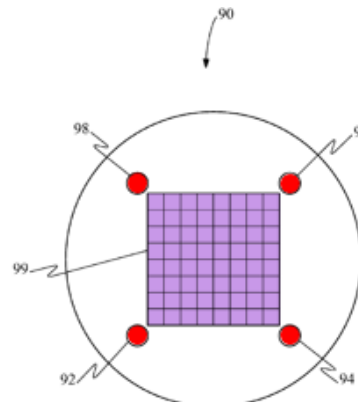


FIG. 7B

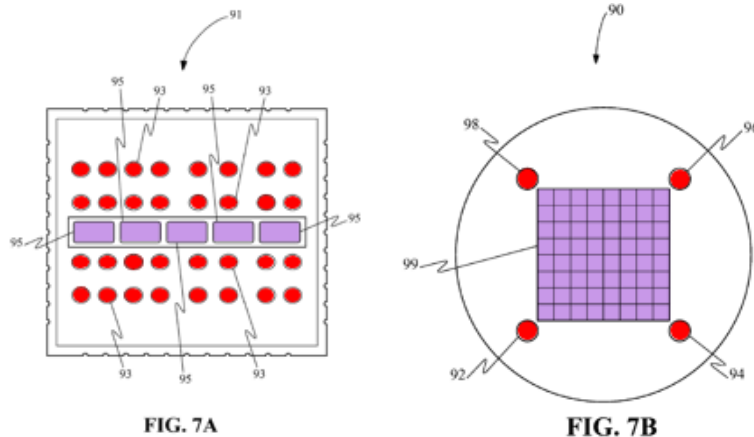
RX-0411 at Figs. 3, 5, and 7A-7B, 9:30-33; Tr. [Warren] 1220:12-1221:8.

A POSITA would have understood that the light sources disclosed in these examples would include at least four emitters, each with a set of three LEDs. Tr. [Warren] 1220:12-1221:8; RX-0411 at 6:38-53, Figs. 3, 5, and 7A-7B; RDX-8.36 (summarizing RX-0411). For example, Figure 3 would include 6 emitters, each with three radial LEDs (where the light sources are *single* LEDs) or 18 light sources, each with three LEDs in a set (where the light sources are *sets* of LEDs). See

Tr. [Warren] 1220:12-1221:8. Figures 5 and 7A similarly demonstrate four or more emitters, each with three or more LEDs, whether the circles that mark individual light sources are single LEDs or sets of LEDs. And Figure 7B demonstrates four emitters, each with a set of three LEDs, when the sources are sets of LEDs.

Limitation [19B]: Lumidigm discloses “*four photodiodes arranged within the user-worn device.*”

The concept of using four or more photodiodes was also well-known. Tr. [Warren] 1191:24-1192:22, 1221:9-15. Lumidigm discloses that its sensor can include any number and arrangement of photodiodes, including in its wristwatch embodiment, for the reasons discussed above for '501 claim 1, limitation [1B]. *E.g.*, RX-0411 at 11:60-12:2. Lumidigm further discloses multiple illustrative examples with “four photodiodes” or more, including in Figures 7A (five photodiodes in a linear array) and 7B (64 photodiodes arranged in rows and columns):



RX-0411 at Figs. 7A-7B, 6:54-63; RDX-8.37 (summarizing RX-0411); Tr. [Warren] 1221:10-15.

Lumidigm also discloses that the four photodiodes are “*arranged within the user-worn device*” for the reasons discussed above for '501 claim 1, limitation [1B].

Lumidigm also discloses that these four photodiodes are “*configured to receive light after at least a portion of the light has been attenuated by the tissue of the user*” for the reasons

discussed above for '501 claim 1, limitation [1B]. For example, Lumidigm explains that the light detectors are “disposed relative to the light sources to detect light from the light sources that has propagated through the tissue.” RX-0411 at 3:25-28; 7:26-29. A POSITA would have understood that the photodiodes would be configured to receive light attenuated by the tissue of the user. Tr. [Warren] 1209:19-1210:11.

Limitation [19C]: Lumidigm discloses “*a protrusion comprising a convex surface*” for the reasons discussed above for '501 claim 1, limitation [1C].

Lumidigm discloses “*separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes*” for the reasons discussed above for '501 claim 1, limitations [1D], [1E].

Lumidigm discloses “*the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue*” for the reasons discussed above for '501 claim 1, limitation [1E]. For example, Lumidigm expressly confirms that the openings over the photodiodes are made from “optically opaque material 37,” that this configuration “minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue,” and that “[o]ther equivalent means of optical blocking can be readily established by one of ordinary skill in the art”:

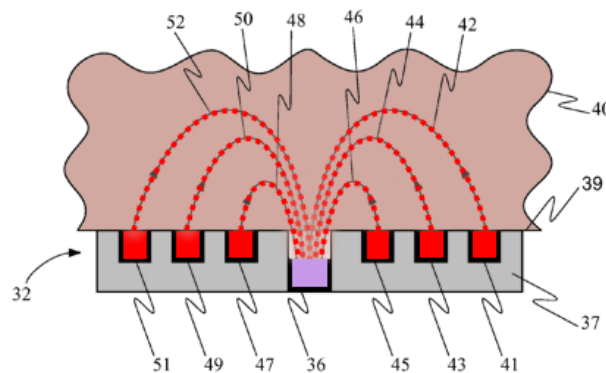


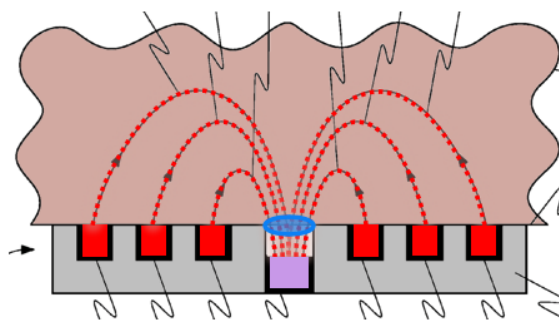
FIG. 2

RX-0411 at Fig. 2, 8:1-11; Tr. [Warren] 1212:11-1213:3. RDX-8.29 (summarizing RX-0411). Lumidigm further explains that the sensor can have a “reflectance geometry” so that “when the tissue is illuminated by a particular light source 41, the resulting signal detected by the detector 36 contains information about the tissue optical properties along a path between the source 41 and detector 36.” RX-0411 at 7:12-14, 7:26-29.

A POSITA would have also understood that Lumidigm’s use of openings made from opaque material has the benefit of allowing light to pass through to the photodiodes while reducing light piping, or the amount of light reaching the photodiodes without being attenuated by the tissue. Tr. [Warren] 1212:11-1213:3.

Limitation [19D]: Lumidigm discloses “*optically transparent material within each of the openings.*”

The use of windows or other optically transparent materials, within or across openings over photodiodes, was also “well-known.” Tr. [Warren] 1221:16-12:22-9, 1193:24-1194:14. Consistent with this well-known idea, Lumidigm explains that its sensor can incorporate “an optical relay (not shown) between the sensor surface 39 and the skin 40” that “transfers the light . . . from the skin back to the detector(s),” and that this optical relay can include “fiber optic face plates,” “individual optical fibers,” and “fiber bundles.” RX-0411 at 8:19-26. Professor Warren illustrates this optical relay in blue in Figure 2:



RX-0411 at Fig. 2; Tr. [Warren] 1221:16-1222:16; RDX-8.38 (summarizing RX-0411).

A POSITA would have understood that fiber optic face plates, individual optical fibers, and fiber bundles were well-known in the art, typically made of glass or plastic cladding, and could be placed within or arranged over the openings. Tr. [Warren] 1221:16-1222:25. A POSITA would have recognized, and Lumidigm confirms, that a well-known way to implement a fiber optic face plate would be to place it “between the sensor surface 39 and the skin” to cover individual openings. RX-0411 at 8:19-21; Tr. [Warren] 1221:16-1222:16. A POSITA would have further recognized that a fiber optic face plate could be implemented as a “single faceplate for multiple openings,” or as “an individual faceplate for each of the individual openings.” Tr. [Warren] 1221:16-1222:9. A POSITA would have recognized that a fiber optic face plate would be beneficial because it would “transfer light” from the tissue to the photodiodes and “protect the detector from dust and debris and dirt.” *Id.* at 1193:24-1194:7, 1221:16-1222:16. A “fiber bundle” would similarly “direct light from a portion of tissue straight to the detector as a means to optimize the detection process.” *Id.* at 1222:10-16.

A POSITA would have thus understood that non-invasive, optical sensing devices should have optically transparent material extending across the openings over the photodiodes and that the benefits would include providing a pathway for attenuated light to pass through to the photodiode while protecting the photodiode from damage or interference caused by contaminants from a user. *Id.* at 1193:24-1194:7, 1221:16-1222:25.

Limitation [19E]: Lumidigm discloses “*one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals*” for the reasons discussed above for 501 claim 1, limitation [1E]. For example, Lumidigm discloses both calculating and outputting measurements based on

signals from the photodiodes. RX-0411 at 3:28-31, 9:58-59, 12:56-13:14, Fig. 9; Tr. [Warren] 1213:4-1214:1. A POSITA would have understood that Lumidigm’s “computational devices” include one or more processors configured to use signals to output measurements of physiological parameters and that the processors could be implemented in a separate reader or integrated onto the same device. Tr. [Warren] 1213:4-1214:1.

Lumidigm also discloses that its processors can output a measurement “*indicative of the oxygen saturation of the user*” for the reasons discussed above for ’502 claim 19, preamble. A POSITA would have recognized that it is the processors in the device that output the measurements associated with Lumidigm’s blood oxygen function. Tr. [Warren] 1215:18-1216:25; RX-0411 at 19:16-19, 19:22-28, Fig. 9; RDX-8.35 (summarizing RX-0411).

(b) ’502 Patent, Claim 20

Lumidigm discloses “[t]he *user-worn device* of claim 19,” for the reasons discussed above for ’502 claim 19.

Lumidigm also discloses “*further comprising a thermistor.*” This limitation relates to the “well-known notion” that “LEDs will change their behavior depending on temperature,” and that if a processor “can receive a temperature signal, in this case from a thermistor, it can adjust the operation of the user worn device.” Tr. [Warren] 1223:1-20. Consistent with this notion, Lumidigm discloses that its sensor may include “additional preprocessing steps” including “performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature” and other factors. RX-0411 at 14:21-28, Fig. 9; RDX-8.39 (summarizing RX-0411). Lumidigm also correctly comments that “[t]hese and other techniques are well-known in the art.” *Id.* at 14:29.

A POSITA would have recognized that a thermistor was one of the “well-known” techniques in the art to perform “explicit corrections” for the “environmental influence[] of temperature,” and it would have been obvious to include a thermistor in Lumidigm’s device to take temperature readings so the processor could use that temperature signal to adjust operations. Tr. [Warren] 1223:1-20.

(c) ’502 Patent Claim 21

Lumidigm discloses “[t]he *user-worn device* of claim 20,” for the reasons discussed above for ’502 claim 20.

Lumidigm discloses “*wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.*” As discussed above for ’502 claim 20, Lumidigm discloses “performing explicit corrections” to account for “environmental influences of temperature” and confirms this is “well known in the art.” RX-0411 at 14:21-29, Fig. 9; RDX-8.39 (summarizing RX-0411). Moreover, as discussed above in connection with ’501 claim 1, limitation [1E], Lumidigm repeatedly refers to its sensor’s processors throughout the specification. *E.g.*, RX-0411 at 12:61-67, Fig. 9. A POSITA would have understood that adjusting operations based on temperature requires, in addition to the thermistor, one or more processors to receive the temperature signal from the thermistor and to adjust operation of the sensor responsive to the temperature signal. Tr. [Warren] 1223:1-20.

(d) ’502 Patent, Claim 22

Lumidigm discloses “[t]he *user-worn device* of claim 21,” for the reasons discussed above for ’502 claim 21.

Lumidigm also discloses “*wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs,*” for the reasons discussed above for ’502 limitation [19A]. The illustrative examples discussed in connection with ’502 limitation [19A] include four emitters, each with a respective set of three LEDs. Tr. [Warren] 1220:13-1221:6.

(4) ’502 Patent, Claim 28

Lumidigm discloses all limitations of ’502 claim 28 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1224:3-1227:21.

Limitation [28Preamble]: Lumidigm discloses “[a] *user-worn device configured to noninvasively measure an oxygen saturation of a user, the user-worn device comprising*” for the reasons discussed above for ’502 claim 19, preamble.

Limitation [28A]-[28B]: Lumidigm discloses “*a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength*” and “*a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength.*”

As discussed above, the concept of including multiple emitters in an optical sensor, each comprising a set of LEDs, has been known for at least thirty years. Tr. [Warren] 1191:7-22, 1195:10-12. Each set of LEDs would include “for example, three LED dies,” and “multiple wavelengths would be present, for example, in a multi-chip LED package.” *Id.* at 1190:25-1191:6, 1205:1-11, 1224:23-1225:5.

Consistent with this “well-known idea,” (Tr. [Warren] 1224:23-1225:5), Lumidigm discloses that its sensor can include any number and arrangement of LEDs, including sets of LEDs, and including in its wristwatch embodiment, for the reasons discussed above for ’501 claim 1, limitation [1A], ’502 claim 19, limitation [19A], and ’502 claim 22. Lumidigm further explains that the light sources “can include some sources that have the same wavelengths as others and some sources that are different” and can include “sets of LEDs . . . with differing wavelength characteristics.” RX-0411 at 6:38-53.

A POSITA reading Lumidigm would have understood that its sensor could include sets of LEDs; that those sets of LEDs could include LEDs of the same variety of differing wavelengths; and that a multi-chip LED package (a “source” in Lumidigm), commonly used at the time, could encapsulate a plurality of LED dies at multiple different wavelengths. Tr. [Warren] 1190:25-1191:6, 1224:9-1225:12.

Lumidigm provides multiple specific examples including the recited “first set” and “second set” of LEDs, which are “spaced apart” from each other, and which include LEDs configured to emit at a “first wavelength” and a “second wavelength,” including the examples in Figures 3, 5, 6, 7A, and 7B:

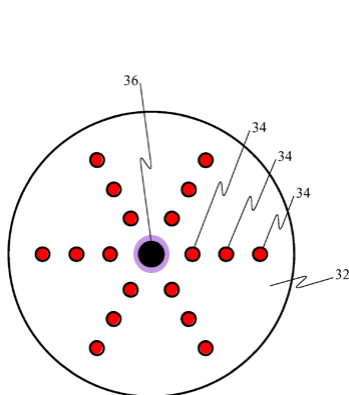


FIG. 3

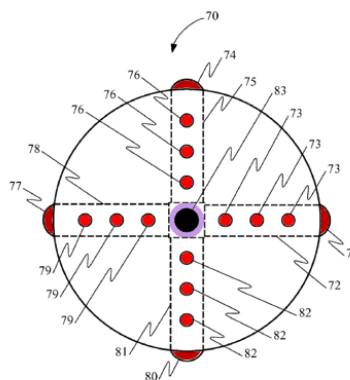


FIG. 5

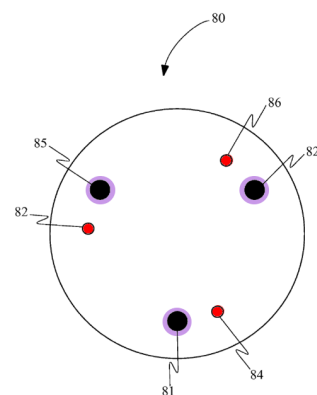


FIG. 6

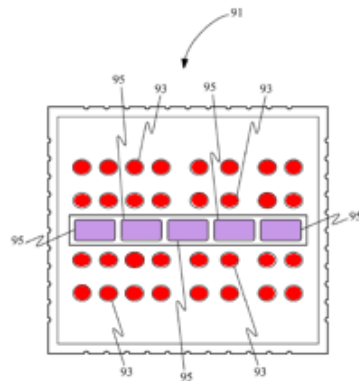


FIG. 7A

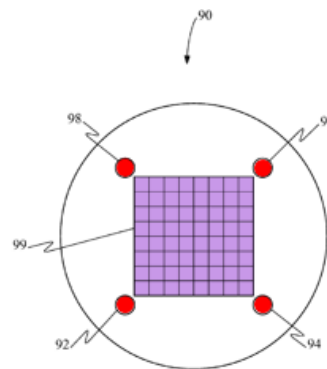


FIG. 7B

RX-0411 at Figs. 3, 5-6, and 7A-7B; Tr. [Warren] 1224:9-1225:12; RDX-8.42-RDX-8.43 (summarizing RX-0411). A POSITA would have understood, consistent with Lumidigm's disclosures, that each light source in these figures could comprise a set of LEDs, and that these sets of LEDs would be spaced apart from each other as shown in the figures. *Id.* at 6:38-53; Tr. [Warren] 1224:9-1225:12. A POSITA would have further understood that each set of LEDs would include LEDs configured to emit at a "first wavelength" and a "second wavelength," so that in each source location "multiple wavelengths would be present" (as in a multi-chip package). *Id.*

Lumidigm also incorporates by reference U.S. Patent Application Ser. No. 10/262,403 (RX-0411 at 1:40-44), which discloses in its Figure 6 multiple sets of LEDs, each with LEDs emitting at "first" and "second" wavelengths. RX-0460 ['403 Application] at Fig. 6, *see also* [0054]. A POSITA would recognize this as an example of the type of "sets of LEDs" that could readily be incorporated into Lumidigm's figures, particularly given that Lumidigm incorporates the application by reference and thus expressly suggests such a combination. Tr. [Warren] 1224:9-1225:12.

Limitation [28C]: Lumidigm discloses "*four photodiodes . . . configured to receive light after at least a portion of the light has been attenuated by the tissue of the user*" for the reasons discussed above for '502 claim 19, limitation [19B].

Lumidigm also discloses that the four photodiodes are “*arranged . . . on an interior surface of the user worn device*” for the reasons discussed above for ’501 claim 1, limitation [1B]. Although this claim specifies four photodiodes rather than three, the same reasoning applies. Tr. [Warren] 1225:13-1226:1.

Lumidigm also discloses that the four photodiodes are “*arranged in a quadrant configuration*.” The concept of arranging photodiodes in a quadrant was also “quite well-known.” Tr. [Warren] 1225:13-1226:1, 1191:24-1192:22, 1195:13-15. Lumidigm explains that its detectors can be implemented “as a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements.” RX-0411 at 6:54-63. A POSITA would have understood that a two-dimensional array would include an arrangement of detectors in a quadrant configuration. Tr. [Warren] 1225:16-1226:1. Lumidigm specifically discloses many more than four photodiodes arranged in a quadrant in Figure 7B and states that “many variations on this configuration exist”:

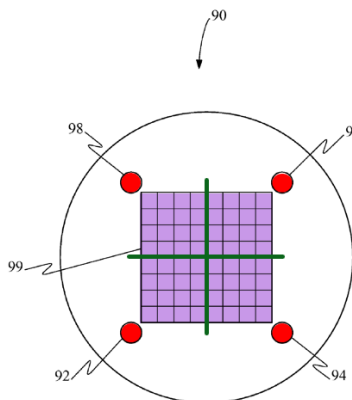


FIG. 7B

RX-0411 at Fig. 7B; RX-0411 at 9:42-45; Tr. [Warren] 1225:13-1226:1; RDX-8.44 (summarizing RX-0411). Figure 7B shows 64 detectors arranged in a quadrant, and a POSITA would recognize that any four of the photodiodes in this figure also could be arranged in a quadrant. Tr. [Warren] 1225:16-1226:1.

Limitation [28D]: Lumidigm discloses “*a thermistor configured to provide a temperature signal*” for the reasons discussed above for ’502 claims 20 and 21.

Limitation [28E]: Lumidigm discloses “*a protrusion arranged above the interior surface, the protrusion comprising: a convex surface*” for the reasons discussed above for ’501 claim 1, limitation [1C].

Limitation [28F]: Lumidigm discloses “*a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes,*” for the reasons discussed above for ’501 claim 1, limitation [1D] and ’502 claim 19, limitation [19C]. A POSITA would have recognized that, for configurations with four or more photodiodes arranged in a quadrant, such as shown in Figure 7B, there would be an opening over each photodiode. Tr. [Warren] 1225:16-1226:1. This claim also specifies that the openings are in the convex surface of the protrusion, but the same reasoning applies as for the earlier limitations. *Id.* at 1224:3-8. Lumidigm teaches that the openings should be located within the convex surface to “incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured.” RX-0411 at 7:57-63. Achieving good “optical coupling” would of course require locating the optical components (including the detectors and associated openings) so that they are aligned with the protrusion’s convex surface. *Id.*; *see also* 8:27-28 (“Optionally, the surface of the light relay can be contoured to fit specific product applications and ergonomic requirements.”).

Lumidigm also discloses “*each opening defined by an opaque surface configured to reduce light piping,*” for the reasons discussed above for ’501 claim 1, limitation [1E] and ’502 claim 19, limitation [19C]. Although this claim references “reducing light piping” rather than “avoiding light piping,” the same reasoning applies. Tr. [Warren] 1224:3-8.

Limitation [28G]: Lumidigm discloses “*a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings*” for the reasons discussed above for ’502 claim 19, limitation [19D]. Although this claim specifies “transmissive windows extending across” the openings rather than “transparent materials within” the openings, the same reasoning applies. Tr. [Warren] 1224:3-8. A POSITA would have recognized that the fiber optic face plates and fiber optic bundles referenced in Lumidigm and discussed in connection with limitation [19D] are transmissive windows and that each would extend across a different one of the openings. Tr. [Warren] 1221:16-1222:25; RX-0411 at 8:19-26.

Limitation [28H]: Lumidigm discloses “*at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities.*” As discussed above, Figure 2 shows a cross-section of Figure 1, illustrating the detectors “recessed from the sensor surface 39 in optically opaque material 37”:

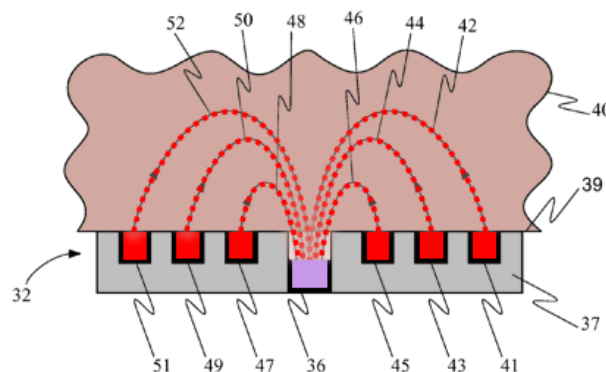


FIG. 2

RX-0411 at Fig. 2, 8:1-4; RDX-8.45 (summarizing RX-0411). Lumidigm expressly states, and a POSITA would have understood, that detector 36 in Figures 1 and 2 is representative and that it may comprise “a plurality of discrete elements.” RX-0411 at 6:54-56, *see also* 3:9-11; Tr. [Warren] 1205:1-11. A POSITA would have further understood that there would be opaque walls

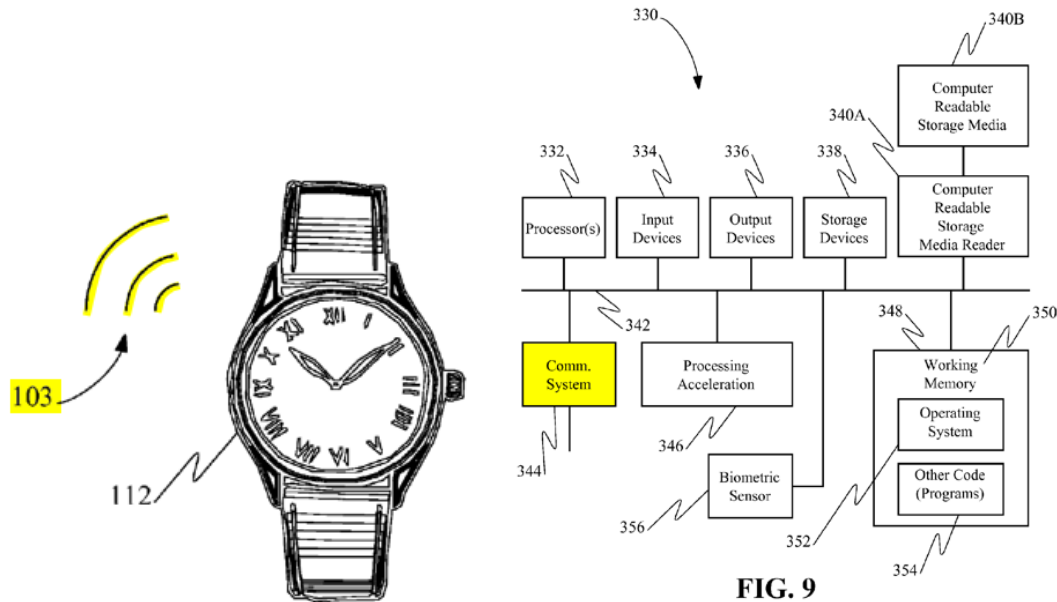
between the interior surface of the sensor and the protrusion, thereby forming cavities or recesses where the respective photodiodes are located. Tr. [Warren] 1226:2-8; RX-0411 at 8:1-11, Fig. 2.

Lumidigm further discloses that “*the photodiodes are arranged on the interior surface within the cavities*” for the reasons discussed above and for ’501 claim 1, limitation [1B] and ’502, claim 28, limitation [28C].

Limitation [28I]: Lumidigm discloses “*one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user*” for the reasons discussed above for ’502 claim 19, limitation [19E].

Lumidigm also discloses “*the one or more processors further configured to receive the temperature signal*” for the reasons discussed above for ’502 claim 21.

Limitation [28J]: Lumidigm discloses “*a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network.*” By the time of the Poeze Patents, the use of wireless communications for sensors was also a “well-known idea.” Tr. [Warren] 1226:9-21. Lumidigm repeatedly confirms that its sensors communicate measurements through wireless communication means. RX-0411 at 11:38-42, 13:9-12, Fig. 8B. Lumidigm also discloses that its devices have a “communication system 344” and that it “may comprise a wired, wireless, modem, and/or other type of interfacing connection and permits data to be exchanged with external devices.” *Id.* at 13:9-12. Lumidigm shows its communications system 344 in Figure 9 and explains that these components can be incorporated into any of its exemplary embodiments including the wristwatch embodiment. *Id.* at Fig. 9, *see also* 12:58-61. Lumidigm also expressly illustrates its watch embodiment with wireless communications 103:



RX-0411 at Figs. 8B and 9; RDX-8.46 (summarizing RX-0411). Lumidigm further explains the wristwatch embodiment's wireless communications capabilities in connection with the fob embodiment, which the patent describes as having identical operation to the wristwatch embodiment (including the wireless RF signals 103 shown in Figure 8B). RX-0411 at 11:38-42, 11:60-12:2.

A POSITA would have understood that a device with a “wireless . . . type of interfacing connection” (RX-0411 at 13:9-12) would have a network interface for wirelessly communicating the measurement of a physiological parameter, including oxygenation levels, to a mobile phone or computer network. *Id.* at 11:38-42, 19:22-28, Figs. 8B and 9; Tr. [Warren] 1226:9-21.

Further, Lumidigm also discloses that its processors can output a measurement indicative of “oxygen saturation” for the reasons discussed above for 502 claim 19, limitation [19E].

Limitation [28K]: Lumidigm discloses “a *user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user.*” The use of user interfaces with touch screens was also

“well known” by the time of the Poeze Patents. Tr. [Warren] 1226:23-1227:3. Lumidigm discloses embodiments of portable electronic devices that were well known to have touch-screens—a mobile phone and a PDA—and explains that those devices “display the retrieved information on the portable electronic device” in connection with Figures 8D and 8E. RX-0411 at 21:29-33; RDX-8.47 (summarizing RX-0411).

A POSITA would have understood from these disclosures that the recited user interface with a touch-screen display could be incorporated into any of the sensor embodiments, including the wristwatch embodiment. Tr. [Warren] 1226:23-1227:7.

Limitation [28L]: Lumidigm discloses “*a storage device configured to at least temporarily store at least the measurement.*” Lumidigm repeatedly refers to processing, measurement, acquisition, and use of information, and a POSITA would recognize that such a device would require memory, another well-known idea, to carry out these operations. RX-0411 at Fig. 9; Tr. [Warren] 1227:9-14. Lumidigm specifically discloses hardware elements, software elements, and storage (including storage device 338, memory 348, and computer-readable storage medium 340*b*) that store measurements taken by the sensor in Figure 9 and the related discussion:

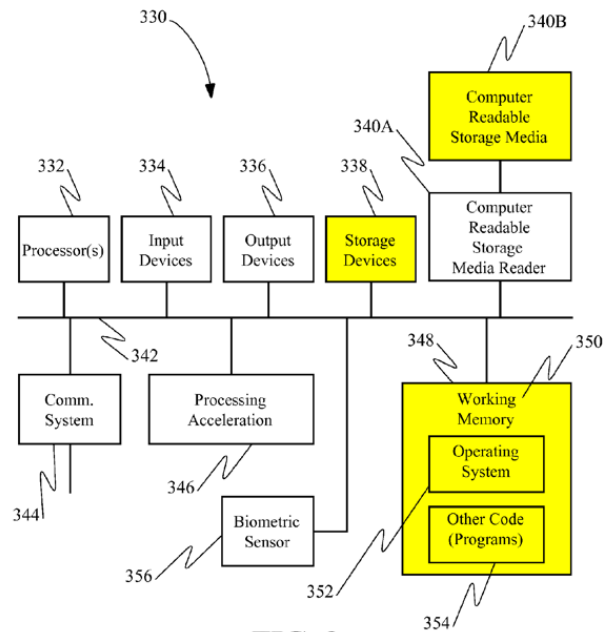


FIG. 9

RX-0411 at Fig. 9, 12:66-13:14; RDX-8.48 (summarizing RX-0411). Lumidigm further discloses that “[t]he storage devices typically hold information defining the stored spectra,” which A POSITA would have understood to mean at least the temporary storage of the measurement (i.e., spectra). RX-0411 at 12:66-13:14; Tr. [Warren] 1227:9-14.

Limitation [28M]: Lumidigm discloses “a *strap* configured to position the user-worn device on the user.” Specifically, Lumidigm discloses a strap for its wristwatch embodiment:

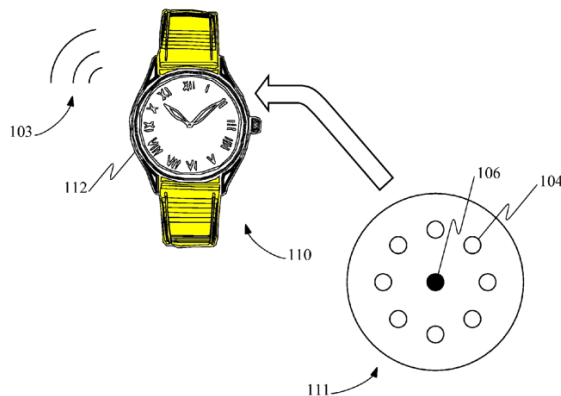


FIG. 8B

RX-0411 at Fig. 8B, 11:60-65; Tr. [Warren] 1227:16-17; RDX-8.49 (summarizing RX-0411).

(5) '648 Patent, Claim 12

Lumidigm discloses all limitation of '648 claim 12 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1227:22-1228:10.

(a) '648 Claim 8

Limitation [8Preamble]: Lumidigm discloses “a *user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising*” for the reasons discussed above for '501 claim 1, preamble.

Limitation [8A]/[8B]: Lumidigm discloses “a *first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength*” and “a *second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength,*” for the reasons discussed above for '502 claim 28, limitations [28A] and [28B].

Limitation [8C]: Lumidigm discloses “*four photodiodes*” for the reasons discussed above for '502 claim 19, limitation [19B] and '502 claim 28, limitation [28C].

Limitation [8D]: Lumidigm discloses “a *protrusion comprising a convex surface*” for the reasons discussed above for '501 claim 1, limitation [1C].

Lumidigm also discloses in “*at least a portion of the protrusion comprising an opaque material*” for the reasons discussed above for '501 claim 1, limitation [1E], and '502 claims 19, limitation [19C], and claim 28, limitations [28F] and [28H]. Although this claim specifies that a portion of the protrusion comprises opaque material, rather than the surfaces of the openings or a wall, the same reasoning applies. Tr. [Warren] 1227:22-1228:2. Lumidigm explains that “the

body of the sensor head 32,” which includes the protrusion, is made from “optically opaque material 37” to provide “optical blocking” and minimize unwanted light. RX-0411 at 8:1-11.

Limitation [8E]: Lumidigm discloses “*a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes*” for the reasons discussed above for ’501 claim 1, limitation [1D], ’502 claim 19, limitation [19C], and ’502 claim 28, limitation [28F]. The same reasoning applies. Tr. [Warren] 1227:22-1228:2.

Limitation [8F]: Lumidigm discloses “*a separate optically transparent window extending across each of the openings*” for the reasons discussed above for ’502 claim 19, limitation [19D] and ’502 claim 28, limitation [28G]. Although this claim specifies a “separate optically transparent window” across each opening, rather than transparent material or a transmissive window, the same reasoning applies. Tr. [Warren] 1227:22-1228:2. A POSITA would have recognized that the fiber optic face plates and fiber bundles referenced in Lumidigm and discussed in connection with above limitations are optically transparent windows and that each would extend across a different one of the openings. Tr. [Warren] 1221:16-1222:25.

Limitation [8G]: Lumidigm discloses “*one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user*” for the reasons discussed above for ’502 claim 19, Limitation [19E].

Limitation [8H]: Lumidigm discloses “*a housing*.” For example, Lumidigm discloses that, for its wristwatch embodiment, “the biometric reader 111 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin in the area of the wrist.” RX-0411 at 11:60-64, Fig. 8B; Tr. [Warren] 1228:3-6; RDX-8.52 (summarizing RX-0411).

Limitation [8I]: Lumidigm discloses “*a strap configured to position the housing proximate tissue of the user when the device is worn*” for the reasons discussed above with respect to claim 28, limitation 28[M].

(b) '648 Claim 12

Lumidigm discloses “[t]he user-worn device of claim 8,” for the reasons discussed above for '648 claim 8.

Lumidigm discloses “*wherein the physiological parameter comprises oxygen or oxygen saturation*” for the reasons provided above with respect to claim '502 claim 19, preamble.

(6) '648 Patent, Claims 24 and 30

Lumidigm discloses all limitations '648 claims 24 and 30 and anticipates these claims or, at a minimum, renders them obvious. Tr. [Warren] 1228:11-1229:14.

(a) '648 Claim 20

Limitation [20Preamble]: Lumidigm discloses “[a] user-worn device configured to non-invasively determine measurements of a user’s tissue, the user-worn device comprising” for the reasons discussed above with respect to '501 claim 1, preamble.

Limitation [20A]: Lumidigm discloses “*a plurality of light emitting diodes (LEDs)*” including for the reasons discussed above for '501 claim 1, limitation [1A].

Limitation [20B]: Lumidigm discloses “*at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user*” for the reasons discussed above for '502 claim 19, limitation [19B] and '502 claim 28, limitation [28C]. Although this claim specifies that the four photodiodes are “arranged to capture light at different quadrants of tissue of a user,” rather than being arranged “in a quadrant configuration,” the same reasoning applies. Tr. [Warren] 1228:11-15.

Limitation [20C]: Lumidigm discloses “*a protrusion comprising a convex surface*” for the reasons discussed above for ’501 claim 1, limitation [1C], ’502 claim 19, limitation [19C], and ’502 claim 28, limitations [28E].

Limitation [20D]: Lumidigm discloses “*a plurality of through holes . . . arranged over a different one of the at least four photodiodes*” for the reasons discussed above for ’501 claim 1, limitation [1D], ’502 claim 19, limitation [19C] and ’502 claim 28, limitations [28F]. Although this claim refers to “through holes” rather than “openings,” the same reasoning applies. Tr. [Warren] 1211:10-1212:10, 1224:3-8, 1227:22-1228:2.

Lumidigm also discloses “*each through hole including a window*” for the reasons discussed above for ’502 claim 19, limitation [19D] and ’502 claim 28, limitation [28G].

Limitation [20E]: Lumidigm discloses “*one or more processors configured to receive one or more signals from the at least one of the photodiodes and determine measurements of oxygen saturation of the user*” for the reasons discussed above for ’502 claim 19, limitation [19E].

(b) ’648 Patent, Claim 24

Lumidigm discloses ’648 claim 24, which recites “*[t]he user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping*” for the reasons discussed above for ’501 claim 1, limitation 1[E] and ’502 claim 28, limitation [28F]. Although this claim references “substantially preventing light piping,” rather than “reducing” or “avoiding light piping,” the same reasoning applies. Tr. [Warren] 1228:16-23. Lumidigm explains that “the body of the sensor head,” which includes the protrusion, is made from “optically opaque material” and that the detectors are recessed from the sensor surface in this optically opaque material to provide “optical blocking” and to “minimize” “shunted” light and other unwanted light from reaching the detectors. RX-0411 at 7:64-8:10. Lumidigm further

explains that “[o]ther equivalent means of optical blocking can be readily established by one of ordinary skill in the art.” *Id.* at 8:10-11. A POSITA would have understood that the use of opaque material has the benefit of allowing light to pass through to the photodiodes while reducing light piping and other forms of optical noise. Tr. [Warren] 1212:11-1213:3, 1228:16-23; RDX-8.55 (summarizing RX-0411). Lumidigm specifically discusses using opaque material to provide “optical blocking” for “shunted” light, and light shunting is another term for light piping. Tr. [Warren] 1212:22-1213:3.

Significantly, the Poeze specification attributes its asserted reduction in light piping to the fact its protrusion is made from opaque material. *E.g.*, JX-001 [’501 patent] at 7:65-8:8, 37:51-52. If the Poeze Patents’ use of opaque material is sufficient to support the claims, then Lumidigm’s use of opaque material also meets the claim language. *See* Tr. [Warren] 1202:19-1203:9; RDX-8.17 (summarizing JX-001).

(c) ’648 Patent, Claim 30

Lumidigm discloses ’648 claim 30, which recites “[t]he user-worn device of claim 20, wherein the protrusion comprises one or more chamfered edges.” The use of chamfered edges was also a “well-known mechanical principle.” Tr. [Warren] 1228:24-1229:10. Lumidigm explains its sensor head can have essentially any shape, “including oval, square and rectangular shapes.” RX-0411 at 7:57-63. Lumidigm also shows beveled edges on the top face of its watch in Figure 8B. A POSITA would have recognized that this type of edge also could be used for the sensor head. Tr. [Warren] 1228:24-1229:10. It would have been obvious to a POSITA that a protrusion for a user-worn device should have chamfered edges, as it was well-known in the art that a sensor that comes in contact with tissue should “incorporate ergonomic features” to increase comfort and optimally contact the user’s tissue. Tr. [Warren] 1228:24-1229:10; RX-0411 at 7:57-

63 (referencing desirability of “incorporat[ing] ergonomic features” into sensor head); RDX-8.56 (summarizing RX-0411).

c. Obviousness Under 35 U.S.C. § 103(a)

Although Lumidigm alone discloses all limitations of the asserted claims, the following combinations also alternatively render the asserted claims obvious:

Combinations	Asserted Claims of Poeze Patents Rendered Obvious
Lumidigm + Seiko 131 + Cramer	All claims
Lumidigm + Webster Lumidigm + Seiko 131 + Cramer + Webster	’502 claim 22
Lumidigm + Webster + Apple ’047 Lumidigm + Seiko 131 + Cramer + Webster + Apple ’047	’502 claim 28

See Tr. [Warren] 1229:11-1243:4. Seiko 131 and Cramer are wristwatch-based sensors, like Lumidigm, and teach most disputed limitations. Webster also teaches the “thermistor” limitations of ’502 claims 22 and 28, and Apple ’047 teaches the “user interface comprising a touch screen display” limitation of ’502 claim 28. *Id.*

(1) Lumidigm in View of Seiko 131 and Cramer Render Obvious All Asserted Claims

U.S. Patent No. 5,766,131 (“Seiko 131”), titled “Pulse-Wave Measuring Apparatus,” was filed July 30, 1996, issued June 16, 1998, and discloses a user-worn “wristwatch type” light-based sensor for physiological measurements. RX-0666 at Abstract; Tr. [Warren] 1230:18-1231:8; RDX-8.61-RDX-8.62 (summarizing RX-0666).

U.S. Patent No. 4,224,948 (“Cramer”), titled “Wrist Borne Pulse Meter/Chronometer,” was filed November 24, 1978, issued September 30, 1980, and discloses a light-based physiological

measuring device “worn as an ordinary wristwatch.” RX-0670 at Abstract; *see* Tr. [Warren] 1231:9-1232:9. Cramer identifies as a “suitable detector” the CLT 2160 photodiode. RX-670 at 5:33-34; RX-1221 [CLT 2160 Data Sheet]; RDX-8.63-RDX-8.65 (summarizing RX-0670, RX-1221).

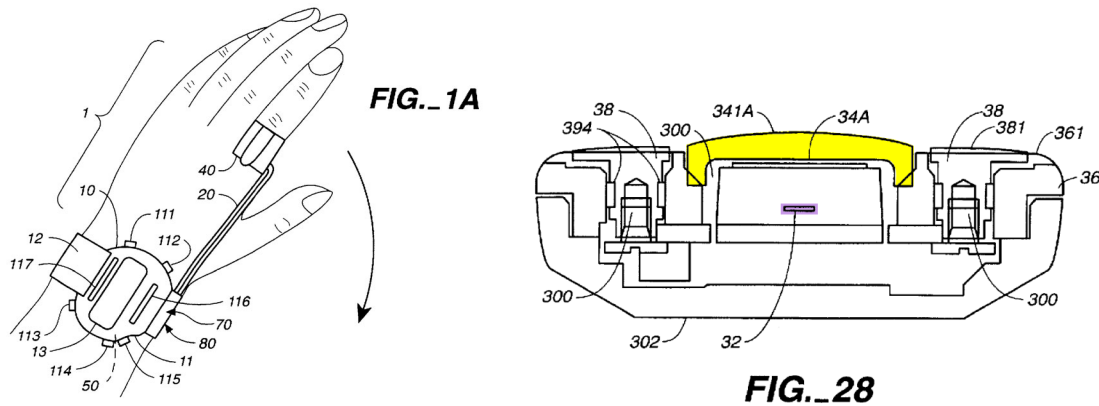
Lumidigm, Seiko 131, and Cramer are analogous art in the same field of wearable, wristwatch-based physiological measuring devices, and a POSITA would have been motivated to modify Lumidigm’s wristwatch based on the relevant teachings of Seiko 131 and Cramer, including the teachings in subsections (a) through (d) below, and would have had a reasonable expectation of success in doing so. Tr. [Warren] 1237:4-1238:6.

- (a) **A “protrusion comprising a convex surface” (’501 claim 12 [1C], ’502 claims 22 [19C] and 28 [28E], ’648 claims 12 [8D], 24 [20C], and 30 [20C]) and a protrusion with “an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape” (’501 claim 12 [12])**

The use of a protrusion with a convex surface, configured to contact the tissue of the user and conform the tissue into a concave shape, was “well-known” in the art at the time the Poeze Patents were filed, dating back to at least the “early 70s,” and was disclosed in multiple references including, for example, Seiko 131 and Cramer. Tr. [Warren] 1210:13-1211:8, 1194:17-1195:5, 1195:20-22; *see also* § IV.D.1.a (State of the Art), *supra*. Lumidigm itself discloses this limitation. *See* § IV.D.1.b.(2), *supra*. Moreover, a POSITA would naturally look to other references in the field to improve on Lumidigm’s disclosures, and Lumidigm *expressly suggests* such a combination in its teaching that its sensor head “*may also have a compound curvature on the optical surface* to match the profile of a device in which it is mounted, to incorporate ergonomic features that

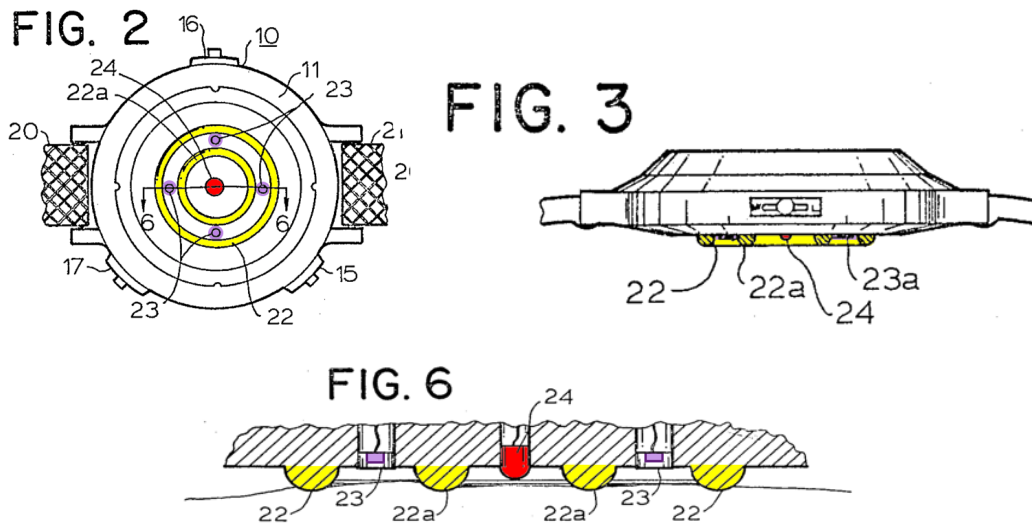
allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons.” RX-0411 at 7:57-63; Tr. [Warren] 1210:13-1211:8, 1233:1:14.

Seiko 131 and Cramer both disclose these limitations. Seiko 131 discloses a wristwatch-based non-invasive physiological sensor with a **convex protrusion**. In the Figure 28 embodiment, the outside surface of the light transmittance plate 341A has a convex curve:



RX-0666 at Figs. 1A and 28, 3:22-28, 19:5-8; Tr. [Warren] 1232:10-20; RDX-8.67-RDX8.68 (summarizing RX-0666). Seiko 131 describes this convex protrusion as “improving” contact between the light transmittance and the tissue. RX-0666 at 3:22-28, 19:5-8; Tr. [Warren] 1245:17-1246:3.

Cramer also discloses these limitations. Cramer, like Seiko 131, discloses a wristwatch-based non-invasive physiological sensor with a protrusion with a **convex surface**:



RX-0670 at Figs. 2, 3, and 6, 5:45-51; Tr. [Warren] 1232:21-25; RDX-8.67-RDX-8.68 (summarizing RX-0670). Cramer also recognizes the benefits of its protrusion as “providing a relatively large area of intimate contact with the user’s wrist” and “insuring both comfortable wearing and sufficient contact” for effective sensing. RX-0670 at 5:45-51, Figs. 3 and 6; Tr. [Warren] 1245:17-1246:12.

A POSITA would have understood that, when a protrusion has a convex surface, the outermost surface of this protrusion will conform the user’s tissue into a concave shape when it contacts the user’s tissue. Tr. [Warren] 1214:2-11, 1232:10-1232:25.

A POSITA would have been motivated to combine Lumidigm’s watch with Seiko 131’s and Cramer’s teachings of protrusions with convex surfaces because (1) Lumidigm expressly suggests the combination in stating that its protrusion can have a “compound curvature” (RX-0411 at 7:58-63); and (2) a POSITA would have independently looked to literature like Seiko 131 and Cramer for the shape of a protrusion as the benefits were well-known, and in fact, Seiko 131 and Cramer themselves state these benefits and suggest including this feature in a watch. Tr. [Warren] 1233:1-14, 1245:17-1246:3; RDX-8.68 (summarizing RX-0411, RX-0666, RX-0670). Indeed,

Seiko 131 and Cramer both teach the benefits of adding a convex protrusion, both generally and on a wrist-based sensor. RX-0666 at 3:22-28, Figs. 1A and 28; RX-0670 at 5:45-51, Figs. 1 and 6.

- (b) A plurality of “openings” or “through holes,” that are “positioned” or “arranged” over or “aligned with the photodiodes,” and that each include “an opaque lateral surface” or are “lined with opaque material,” that is configured to “avoid” or “reduce light piping” or to “reduce an amount of light reaching the photodiodes without being attenuated by the tissue” (’501 claim 12 [1D-E], ’502 claims 22 [19C] and 28 [28F], ’648 claims 12 [8E], 24 and 30 [20D]), and a “protrusion compris[ing] opaque material configured to substantially prevent light piping” (’648 claims 24 and 30 [24]).

The use of openings or through holes, positioned or arranged over or aligned with photodiodes, including openings or through holes with opaque lateral surfaces or lined with opaque material configured to provide optical blocking, to reduce, avoid, or substantially prevent light piping, and to reduce an amount of light reaching the photodiodes without being attenuated by tissue, was also “well-known” in the art at the time the Poeze Patents were filed, dating back to the “late 60s,” and was disclosed in multiple references including, for example, Seiko 131 and Cramer. Tr. [Warren] 1211:10-1212:3, *see also* 1192:25-1193:6; § IV.D.1.a (State of the Art), *supra*. Lumidigm itself discloses these limitations. *See* § IV.D.1.b.(2), *supra*. Moreover, a POSITA would naturally look to other references in the field to improve on Lumidigm’s disclosures, and Lumidigm expressly suggests such a combination in its teaching that its sensor head includes detectors “*recessed from the sensor surface 39 in optically opaque material 37,*” that this “recessed placement of detector 36 minimizes the amount of light that can be detected after reflecting off the first (epidermal surface of the tissue” and provides “*optical blocking,*” and

that “other equivalent means of optical blocking can readily be established” by a POSITA. RX-0411 at 7:64-8:11, Figs. 2 and 6; Tr. [Warren] 1211:10-1214:1, 1234:10-21.

Seiko 131 discloses these limitations. Seiko 131’s sensor includes a single photodiode, and an **opening** with *opaque lateral surfaces* positioned and arranged over and aligned with that photodiode. RX-0666 at 10:30-36, Fig. 28. Figure 28 shows this opening between the detector and the user’s tissue:

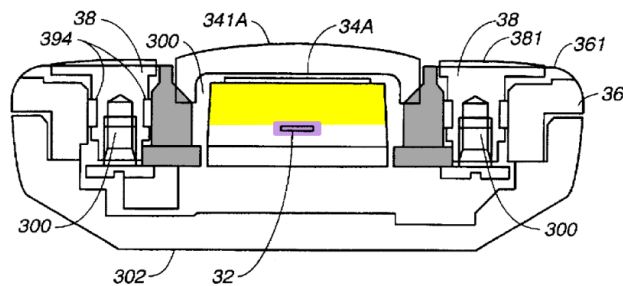
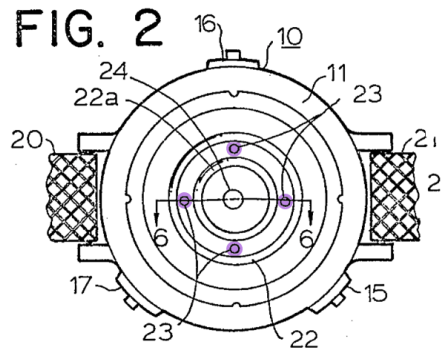


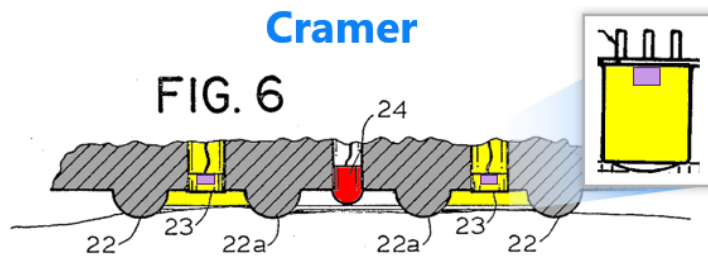
FIG. 28

RX-0666 at Fig. 28. A POSITA would have recognized that, in sensors with multiple photodiodes, there would be similar openings over each photodiode to allow light to reach the photodiodes after it has passed through the user’s tissue. Tr. [Warren] 1212:4-10, *see also* 1211:10-1213:3, 1225:16-1226:1.

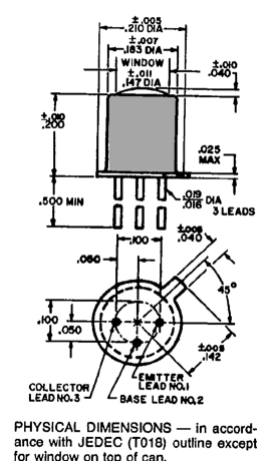
Cramer also discloses these limitations. Cramer’s sensor includes four photodiodes, and separate **openings** with *opaque lateral surfaces* positioned and arranged over each of the four photodiodes. RX-0670 at 5:41-62, Figs. 3 and 6. Cramer states that a “suitable detector” for its embodiments is the Clairex “CLT 2160 photo diode.” *Id.* at 5:33-35; RX-1221 at 1. Cramer describes and its figures show four of the CLT 2160 detectors arranged in a circular array (i.e., a quadrant):



Id. at Fig. 2. A POSITA would recognize the CLT 2160 as a “can” detector and would understand that each can would be made from an opaque material, that the can also would include a lens at the end of the can near the tissue surface, and that there would be a gap between the detector and the lens, creating an opening between the detector and the lens. RX-0670 at Fig 6; RX-1221 at 1; Tr. [Warren] 1231:23-1232:9, 1234:3-8; RDX-8.70 (summarizing RX-0666, RX-0670, RX-1221). This understanding is consistent with Cramer’s disclosures and figures, as well as the data sheet for the CLT 2160 referenced in Cramer’s specification. RX-0670 at 5:33-35, Fig. 6; RX-1221 [CLT 2160 Data Sheet] at 1. There would thus be four detectors, arranged in a quadrant, each aligned with and positioned under an opening:



CLT 2160



RX-0670 at Fig. 6; Tr. [Warren] 1231:23-1232:9, 1233:15-1234:8; RX-1221 at 1.

Cramer further discloses two layers of opaque lateral surfaces around the openings over the photodiodes. The first is formed by “[a] pair of light blocking rings integral with a lower case face isolat[ing] the photo detector from direct view from the light source and from view of the ambient light when the lower face is in contact with the wearer’s body e.g. the wrist.” RX-0670 at 2:46-51, 5:45-51, Fig. 6. These light blocking rings or “bosses” create an opening with opaque lateral surfaces relative to the photodiodes (23). *Id.* at 5:45-51, Fig. 6. Cramer’s canned photodiodes provide “another layer” of opaque surfaces around the openings. Tr. [Warren] 1234:3-8; *see also* RX-1221. Cramer’s sensor body thus has a protrusion, with the recited openings over the photodiodes, and with two layers of opaque lateral surfaces— the bosses are opaque and the walls around the cans are also opaque. *See* Tr. [Warren] 1231:15-1232:9, 1233:15-1234:8; RDX-8.70-RDX-871 (summarizing RX-670, RX-1221).

A POSITA would have understood that the use of openings over photodiodes, constructed with opaque lateral surfaces or lined with opaque materials, reduce, avoid, and substantially prevent light piping. Tr. [Warren] 1202:19-1203:9, 1211:10-1213:3, 1234:10-21. In fact, the Poeze specification attributes its purported reduction in light piping to the fact that its protrusion is made from opaque material. *E.g.*, JX-001 [’501 patent] at 7:65-8:8, 37:51-52.

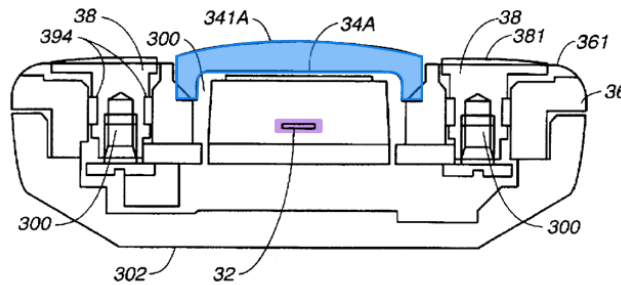
A POSITA would have been motivated to combine Lumidigm’s wristwatch with these teachings from Seiko 131 and Cramer because (1) Lumidigm expressly teaches that its sensor should have openings over photodiodes, made with opaque materials, to avoid light shunting and provide optical blocking (RX-0411 at 7:64-8:11) ; and (2) a POSITA would have independently looked to literature like Seiko 131 and Cramer for these elements as the benefits were well-known, and in fact, Seiko 131 and Cramer themselves state these benefits and suggest including this feature

in a watch. RX-0666 at Fig. 28; RX-0670 at Fig. 6; Tr. [Warren] 1234:10-21; RDX-8.71 (summarizing RX-0411, RX-0666, RX-0670).

- (c) **“Optically transparent material within each of the openings” (’502 claim 22 [19D]), “transmissive” or “optically transparent windows,” each “extending across” a different one of the openings (’502 claim 28 [28G], ’648 claim 12 [8F]), and “each through hole including a window and arranged over a different one of the last least four photodiodes” (’648 claims 24 and 30 [20D])**

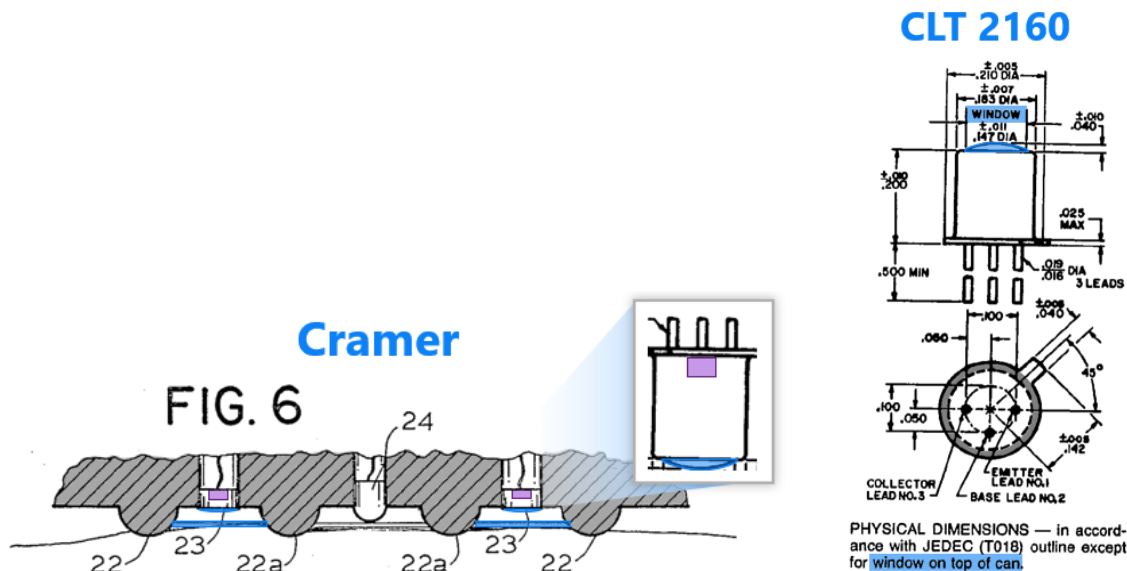
The use of optically transparent materials within or transmissive or transparent windows extending across openings over photodiodes also was “well-known” in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Seiko 131 and Cramer. Tr. [Warren] 1221:16-12:22-9, 1193:24-1194:14; *see also* § IV.D.1.a (State of the Art), *supra*. Lumidigm itself discloses this limitation. *See* § IV.D.1.b.(3), *supra*. Moreover, a POSITA would have naturally looked to other references in the field to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination including in its teaching that its sensor “incorporates an *optical relay* (not shown) between the sensor surface 39 and the skin 40,” that this optical relay “transfers the light from the light sources onto the skin and from the skin back to the detector(s) while minimizing light loss and spreading,” and that “methods of performing this function include “*fiber-optic face plates*,” “*fiber bundles*,” and “other mechanisms known to one of skill in the art.” RX-0411 at 8:19-26; Tr. [Warren] 1221:16-1222:25, 1235:14-1236:2.

Seiko 131 discloses these limitations. Seiko 131 describes the use of “light transmittance plate 34, which is a glass plate” over its photodiode. RX-0666 at 10:30-36. This *glass transmittance plate 34* may be convex, and is arranged to form a window over photodiode 32:

**FIG. 28**

RX-0666 at Fig. 28, 3:22-28, 19:5-8; Tr. [Warren] 1234:22-1235:12; RDX-8.73-RDX-8.74 (summarizing RX-0666).

Cramer also discloses these limitations. As discussed above, Cramer discloses four photodiodes, and separate openings positioned and arranged over each of the four photodiodes. Cramer also discloses multiple layers of *transparent windows or coverings* within and extending across the openings. As referenced above, Cramer states that a “suitable detector” for its embodiments is the Clairex “CLT 2160 photo diode.” RX-0670 at 5:33-35; RX-1221 at 1. A POSITA would recognize the CLT 2160 as a “can” detector and would understand that each can would include a lens at the top end of the can, that the detector would be positioned inside the can at the focal point of the lens, and that there would be a gap between the detector and the lens, creating an opening between the detector and the lens. RX-0670 at Fig 6; RX-1221 at 1; Tr. [Warren] 1231:23-1232:9, 1234:3-8, 1234:22-1235:12. Again, this understanding is consistent with Cramer’s disclosures and figures as well as the data sheet for the CLT 2160 referenced in Cramer’s specification. The CLT 2160 data sheet confirms that the CLT 2160 has “planar epitaxial photoresistors in a hermetically sealed TO-18 case,” with a “lens” that forms a “window” at the top of the can and illustrates this with a figure.



RX-0670 at Fig. 6; RX-1221 at 1; Tr. [Warren] 1231:23-1232:9, 1234:3-8, 1234:22-1235:12.

As Cramer's Figure 6 shows, in addition to the windows at the end of cans, Cramer also has a further layer of clear transparent windows between the cans and the tissue. RX-0670 at Fig. 6; Tr. [Warren] 1234:22-1235:12. Cramer thus discloses multiple types of transparent windows or coverings associated with each opening – each can would, at a minimum, have a lens at the end of the can, and there is also a further layer of clear transparent material between the can and the tissue. RX-0670 at Fig. 6; RX-1221; Tr. [Warren] 1231:23-1232:9, 1234:3-8, 1234:22-1235:12; RDX-8.73-RDX-8.74 (summarizing RX-0670, RX-1221).

A POSITA would have been motivated to combine Lumidigm's wristwatch with these teachings from Seiko 131 and Cramer because (1) Lumidigm expressly states that its sensor can include an optical relay (RX-0411 at 8:19-26) ; and (2) a POSITA would have independently looked to literature like Seiko 131 and Cramer for this element as the benefits were well-known. RX-0666 at 3:22-28, 19:5-8, Fig. 28; RX-0670 at Fig. 6; RX-1221; Tr. [Warren] 1235:14-1236:2; RDX-8.74 (summarizing RX-0411, RX-0666, RX-0670).

(d) “Chamfered edges” (’648 claim 30)

The use of chamfered edges also was a “well-known” in the art at the time the ’648 patent was filed, had been around for “many decades,” and was disclosed in multiple references including, for example, Seiko 131 and Cramer. Tr. [Warren] 1228:24-1229:10, 1236:17-1237:3; *see also* § IV.D.1.a (State of the Art), *supra*. Lumidigm itself suggests this limitation. *See* § IV.D.1.b.(6), *supra*. Moreover, a POSITA would naturally look to other references in the field to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination in its teaching that its sensor head can have essentially any shape and can incorporate “ergonomic features.” RX-0411 at 7:57-63; Tr. [Warren] 1228:24-1229:10, 12:36:17-1237:3.

Seiko 131 discloses this limitation. As discussed above, Seiko 131 describe a structure with a transmittance plate, with a convex surface, that conforms the tissue into a concave shape. Seiko 131 also shows chamfered edges in multiple embodiments, including on the light transmittance plate and on other portions of the watch sensor unit, for comfort purposes:

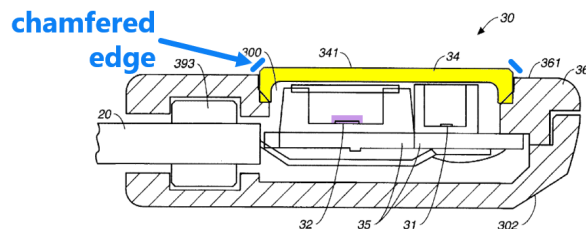
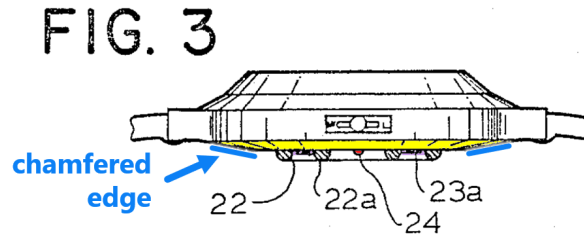


FIG. 5

RX-0666 at Fig. 5. Seiko 131 explains that, when the transmittance plate is convex, this applies pressure and contact with the wrist is improved. *Id.* at 3:22-28, 19:5-8. A POSITA would have understood the advantages of the beveled/chamfered edges in Seiko 131, including to improve user comfort. Tr. [Warren] 1228:24-1229:10, 1236:3-16, 1236:17-1237:3; RDX-8.75-RDX-8.76 (summarizing RX-0666).

Cramer also teaches this limitation. Cramer's Figure 3 illustrates its protrusion with chamfered edges:



RX-0670 at Fig. 3. A POSITA would have understood the advantages of the beveled/chamfered edges in Cramer, such as improvement of user comfort. Tr. [Warren] 1228:24-1229:10, 1236:3-16, 1236:17-1237:3; RDX-8.75-RDX-8.76 (summarizing RX-0670).

A POSITA would have been motivated to combine Lumidigm's wristwatch with these teachings from Seiko 131 and Cramer because (1) Lumidigm expressly states that its sensor head can have various shapes and incorporate ergonomic features, which Professor Warren explained a POSITA would understand to include chamfered edges (RX-0411 at 7:57-63); and (2) a POSITA would have independently looked to literature like Seiko 131 and Cramer for this element as the benefits (including user comfort) were well-known, and in fact, Seiko 131 and Cramer themselves state these benefits and suggest including this feature in a watch. RX-0666 at Figs. 5 and 28; RX-0670 at Fig. 3; Tr. [Warren] 1236:17-1237:3; RDX-8.74 (summarizing RX-0411, RX-666, RX-670).

(e) Motivation to Combine and Reasonable Expectation of Success

Lumidigm expressly suggests using each feature above in subsections (a) through (d), including the recited protrusion with a convex surface, the recited openings over the photodiodes with opaque lateral surfaces and opaque materials to provide optical blocking, the recited transparent materials and windows across the openings, and the recited chamfered edges. It also

expressly suggests that all these features can be included in its wristwatch embodiment. RX-0411 at 11:60-12:2; *see also* Tr. [Warren] 1204:18-1206:7, 1207:23-1208:13, 1214:12-1215:4.

Additionally, each feature was a “well-known [light] management feature” and taught in many prior art references, and a POSITA would have known that the elements would form a “natural combination” and yield predictable results. Tr. [Warren] 1237:4-1238:14. A POSITA would have been further motivated to look at Cramer and Seiko 131, as each are analogous art from the same field of light-based measurement devices, and specifically, each of them was a wristwatch-based device, and a POSITA would have had a reasonable expectation of success in making the combination:

Motivation to Combine/Reasonable Expectation of Success

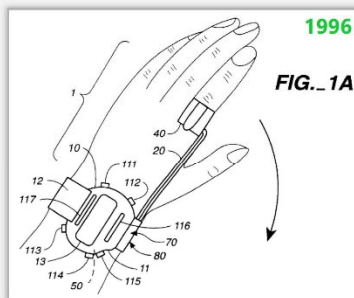


Lumidigm



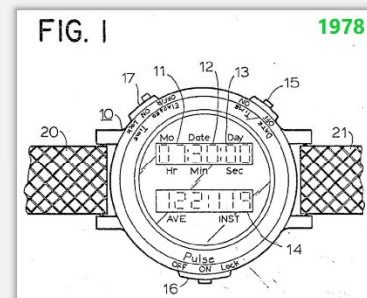
RX-0411 [Lumidigm] at Fig. 8B
(Excerpt)

Seiko 131



RX-0666 [Seiko 131] at Fig. 1A

Cramer



RX-0670 [Cramer] at Fig. 1

RDX-8.77

Tr. [Warren] 1237:4-1238:6; RDX-8.77 (summarizing RX-0411, RX-0666, RX-0670). Moreover, combinations like these already had been made in other prior art devices. Tr. [Warren] 1237:4-16, 1238:1-6; *see also* § IV.D.1.a (State of the Art), *supra*.

Seiko 131 and Cramer focused on pulse rate measurements, but A POSITA would still look to their teachings because the same light management features are employed in pulse oximetry. Tr. [Warren] 1237:17-25. It would have been obvious to a POSITA to look to light-based devices that measure various physiological parameters, including pulse rate and blood oxygen, as all make use of the same general components and techniques. Tr. [Warren] 1193:7-22, 1237:4-1238:6.

A POSITA would have known there are benefits to using a protrusion with a convex surface, including, for example, to provide better coupling and thus better measurements. Lumidigm, Seiko 131, and Cramer all disclose the benefit of having a convex protrusion in improving contact between the user tissue and surface of a sensor and in improving user comfort. RX-0411 at 7:58-63; RX-0666 at 3:22-28, 19:5-8, Fig. 28; RX-0670 at 5:45-51, Figs. 3 and 6. It was well known in the art that sensors with protrusions can improve coupling, and other references in the field included similar teachings. For example, Nippon explains that a protrusion provides a more repeatable coupling effect. RX-0665 [Nippon] at 2:57-62, 5:12-17, Fig. 3b.

A POSITA would have further understood that a convex protrusion would have been desirable to provide slight pressure on the measurement site and yield a more accurate measurement. Tr. [Warren] 1194:17-1195:5, 1211:2-8. For example, when acquiring measurements on a wrist, a POSITA would have known that a protrusion would be a sensible way to increase signal quality by pushing residual blood out of the way to increase the signal-to-noise ratio. *Id.*; *see, e.g.*, RX-0411 at 8:11-14 (“Additionally, a force sensing functionality is sometimes built into the sensor to ensure firm contact between the sensor and the skin, minimizing the amount of shunted light.”); RX-0666 at 10:7-45; RX-670 at 5:16-25, Figs. 3 and 6.

A POSITA would have further recognized that the protrusion would need to have openings or windows so light can travel from the tissue to the photodiodes placed on the interior surface of

the sensor. Tr. [Warren] 1211:10-1213:3, 1225:16-1226:1. A POSITA would have understood the benefits of using openings with opaque lateral surfaces or lined with opaque material, as disclosed in Lumidigm, Seiko 131, and Cramer, so that ambient light and other forms of optical noise would not reach the photodiodes. *Id.* at 1192:25-1193:22, 1203:6-9, 1211:10-1213:3, 1233:15-1234:8; RX-0411 at 8:2-7. A POSITA would have also understood that the advantages include reducing, avoiding, and substantially preventing light piping. *Id.* These concepts were well-known in the art. RX-0411 at 8:1-10, 8:10-11 (“Other equivalent means of optical blocking can be readily established by one of ordinary skill in the art.”); Tr. [Warren] 1192:25-1193:22, 1203:6-9, 1212:4-1213:3.

For example, Lumidigm itself teaches that photodiodes should be recessed in openings with “optically opaque material” to “minimize [] the amount of light that can be detected after reflecting off the first (epidermal) surface” and for “optical blocking” to reduce “shunted” light (i.e., light piping). RX-0411 at 8:1-11, Fig. 2; Tr. [Warren] 1211:10-1212:3. Professor Warren’s own student devices, including Kansas State 6D, confirm that even undergraduate students understood that physiological sensors should include openings over the photodiodes with walls made of opaque material to reduce light mixing. RX-0515; RX-0508 at Fig. 11; RX-504 at 1 (describing the “[o]ptimized [d]esign” of K-State 6D as “[l]ess susceptible to ambient noise due to opaque material and flexible design”); RPX-6; Tr. [Warren] 1200:4-15. Cramer similarly teaches the use of opaque walls surrounding the photodiodes to “isolate the photo detector from direct view from the light source and from the view of the ambient light when the lower face is in contact with the wearer’s body e.g. the wrist” (e.g., RX- 0670 at 2:46-51) and to “prevent[] direct transmission of light between source 24 and detectors 23 (e.g., *id.* at 5:44-48, Figs. 3 and 6). *See* Tr. [Warren] 1233:15-1234:2.

The textbook *Design of Pulse Oximeters* by J G Webster (IOP Publishing Ltd., 1997) (“Webster”), which Complainants’ own expert recognized as an authority on pulse oximetry components and design, also discloses the importance of using opaque materials to minimize ambient light reaching the photodiodes. RX-0035 [Webster] at 111, 201-202, Fig. 3.10; DocID 761612 [Ex. 2, Madisetti Rebuttal Claim Construction Report] at ¶ 9 (describing Webster as “a comprehensive textbook on pulse oximetry”). Webster also provides solutions that minimize ambient light including careful placement of LEDs and photodiodes and the use of light impervious barriers. RX-0035 at 96. Webster specifically recommends that oximeter probes should be manufactured of “black opaque material that does not transmit light, or enclosed in an opaque plastic housing to reduce the possibility of false readings. RX-0035 at 202.

A POSITA would further have recognized that the use of optically transparent material within openings associated with photodiodes, or transmissive windows extending across the openings, would have provided additional benefits including by transferring and directing light and by protecting the photodiodes from damage or interference caused by contaminants, such as hair, sweat/liquid, dirt, debris, etc. Tr. [Warren] 1193:24-1194:7, 1221:16-1222:16. Again, these benefits were also taught by other art in the field. For example, Webster describes a “can package” for a photodiode that seals the photodiode and creates a window for light to pass to the photodiode. RX-0035 at 94, Fig. 6.5(a), *see also* 250, Fig. 3.10, Fig. 6.6, Fig. 13.12. And Haar discloses that closing the contact surface of the measuring head provides protection for the components within. RX-0667 [Haar] at 3:21-23.

A POSITA also would have been motivated to incorporate chamfered edges, for multiple reasons—including, for example, for user comfort and increased sensor contact—and would have had a reasonable expectation of success in doing so. Tr. [Warren] 1228:24-1229:10, 1236:3-

1238:6. Further, A POSITA would have understood that a convex protrusion could have a beveled edge, and that it would provide the expected benefit of minimizing discomfort when a wearable device is pressed against the skin. Tr. [Warren] 1228:24-1229:10, 1236:3-1238:6.

A POSITA would appreciate that all elements discussed above could be combined together in the same device, and would have had a reasonable expectation of success in doing so. Tr. [Warren] 1237:4-1238:6; RDX-8.77 (summarizing RX-0411, RX-0666, RX-0670). A POSITA would have recognized that combining Lumidigm's wristwatch with Seiko 131's and Cramer's wrist-worn teachings would have amounted to nothing more than the use of known techniques to improve similar devices in the same way and that combining the prior art elements according to known methods would yield predictable results. *Id.*

A POSITA would have been motivated to combine Lumidigm with Seiko 131 and Cramer's teachings because the existence, function, and advantages of the recited elements, all basic "light management features," were widely known and had been used in the field for similar light-based physiological sensors before the priority date, including as disclosed in the prior art references relied on above and numerous others. Tr. [Warren] 1237:4-1238:6; *see also* Tr. [Warren] 1189:12-1195:22, 1200:2-15, 1203:6-9. A POSITA would have been able to mix and match these elements in any number of permutations—including the specific combinations recited by the claims—and would have expected predictable and successful results because similar combinations had "already been done in various forms." *Id.* at 1191:7-22, 1237:4-1238:6. In all cases, the combinations would be nothing more than use of familiar elements in accordance with known methods. *Id.* at 1237:4-1238:6; *see also* Tr. [Warren] 1189:12-1195:22, 1200:2-15, 1203:6-9.

**(2) Lumidigm in View of Webster Render Obvious '502
Claim 22**

As referenced above, claim 22 of the '502 patent includes limitations relating to a thermistor (limitation [20]) and a processor to adjust operations based on signals from the thermistor (limitation [21]). For the reasons stated above, Lumidigm alone anticipates or renders obvious claim 22. Alternatively, Lumidigm in combination with Webster renders claim 22 obvious.

Complainants' expert, Dr. Madiseti, has relied on Webster as a leading publication in the field and one with which a POSITA would be familiar. DocID 761612 [Ex. 2, Madiseti Rebuttal Claim Construction Report] at ¶ 9 (describing Webster as "a comprehensive textbook on pulse oximetry"). Professor Warren has had his own personal copy for 20 years. Tr. [Warren] 1239:3-8. A POSITA would have been motivated to modify Lumidigm's wristwatch based on Webster's relevant teachings, and would have had a reasonable expectation of success in doing so. Tr. [Warren] 1238:18-23, 1239:18-1240:3.

- (a) **A "thermistor" and "one or more processors . . . configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal" ('502 claim 22)**

The use of thermistors to output temperature signals and processors to receive those signals and adjust operation based on the signals was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Webster. Tr. [Warren] 1238:18-23. A POSITA would have been familiar with the "well-known notion" that "LEDs will change their behavior depending on temperature." *Id.* at 1223:1-20. A POSITA would have further realized that a thermistor could be used to monitor temperature, and that signals from the thermistor could be used to adjust the calibration of the system, and would have naturally looked to Webster to improve on the disclosures of Lumidigm. Tr. [Warren] 1223:1-20, 1238:15-1240:3; *see also*

Tr. [Sarrafzadeh] 1053:9-1056:23, 1060:2-1062:8. Lumidigm expressly suggests such a combination including in its teaching of “*performing explicit corrections to account for* sensor-to-sensor variations or *environmental influences of temperature*” and that “[t]hese and other techniques are *well known in the art*.” RX-0411 at 14:21-29.

Webster discloses claim 22 limitations [20] and [21] (i.e., incorporated claims 20 and 21). Webster recognizes that temperature changes affect the operation of an LED and that a temperature sensor can compensate for LED temperature changes. RX-0035 at 85. Webster describes how the “temperature information” is fed into the microprocessor and used by the microprocessor to choose calibration curves to match LED wavelengths. *Id.* Webster also recognizes that a thermistor can be used to measure temperature, and includes an example of a sensor with a thermistor for measuring oxygenation:

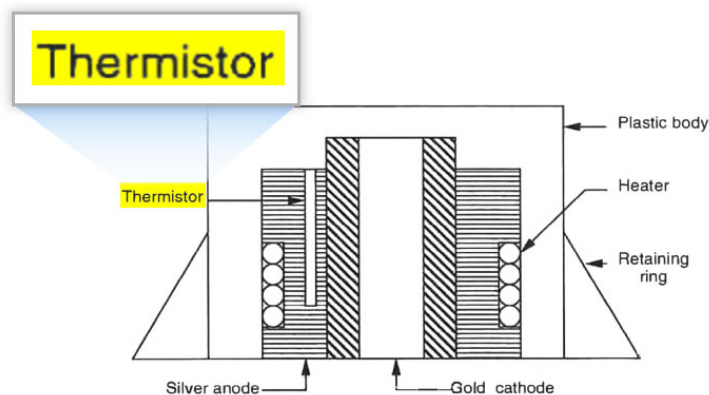


Figure 3.4 A cross section of a transcutaneous PO_2 electrode. The electrolyte below the anode and cathode is held in place by a polypropylene membrane.

Id. at Fig. 3.4; Tr. [Warren] 1238:24-1239:17; RDX-8.80-RDX-8.81 (summarizing RX-0035).

A POSITA would have been motivated to combine Lumidigm’s wristwatch with these teachings from Webster because (1) Lumidigm expressly states that the sensor can perform explicit corrections to account for temperature (RX-0411 at 14:21-29); and (2) a POSITA would have independently looked to literature like Webster for this element as the benefits were well-known,

and in fact, Webster itself states these benefits and suggest including this feature in a physiological measurement device. RX-0035 at 85, Fig. 3.4; Tr. [Warren] 1238:15-1239:8, 1239:18-1240:3, *see also* 1223:1-20; RDX-8.81 (summarizing RX-0411, RX-0035).

(b) Motivation to Combine and Reasonable Expectation of Success

As referenced above, Lumidigm expressly suggests “performing explicit corrections” to account for “environmental influences of temperature” and confirms that “these and other techniques are well known in the art.” *E.g.*, RX-0411 at 14:21-29. It also expressly suggests that these features can be included in its wristwatch embodiment. *Id.* at 11:60-12:2. Additionally, thermistors and processors to adjust operations based on temperature signals from a thermistor were well known and taught in many prior art references, and a POSITA would have known that the elements could have been combined with Lumidigm to yield predictable results. Tr. [Warren] 1238:15-1240:3, *see also* 1223:1-20. A POSITA would have been motivated to use Webster, a leading treatise from the same field of light-based measurement devices. Tr. [Warren] 1238:24-1239:8.

A POSITA would have known that a thermistor would be used to take a temperature measurement of the device and adjust operations and that making corrections in response to a temperature signal would ensure more accurate physiologic measurement. Tr. [Warren] 1238:15-1239:8, *see also* 1223:1-20. A POSITA would have understood the use of a thermistor to compensate for temperature variations in the LEDs during operation of the sensor was well known. *Id.* A POSITA would have had a reasonable expectation of success when using a thermistor to take a temperature measurement and then adjusting operation based on the temperature measurement to achieve a more reliable measurement. *E.g.*, RX-0411 at 14:21-29; RX-0035 at 85, Fig. 3.4; RX-0489 [McCarthy] at 3:24-33; Tr. [Warren] 1238:15-1240:3, *see also* 1223:1-20.

The combination of Lumidigm's wristwatch with Webster's teachings is nothing more than the use of a known technique to improve a similar device in the same way and this combination would yield predictable results. *See* Tr. [Warren] 1238:15-1240:3. Again, the references are in the same field of endeavor and the combination would be used together based on sound engineering principles. *Id.*

**(3) Lumidigm in view of Seiko 131, Cramer, and Webster
Render Obvious Claim 22**

In addition to combining Lumidigm with Webster *alone* for purposes of '502 claim 22 (as discussed above), it also would have been obvious to combine Lumidigm with Seiko 131, Cramer and Webster. Seiko 131 and Cramer teach the recited protrusion with a convex surface, openings lined with opaque material, and optically transparent material within the openings [limitations [C] and [D]], and Webster teaches the recited thermistor and processor to adjust operations (limitations [20] and [21]). A POSITA would have been motivated to modify Lumidigm's wristwatch based on these teachings of Seiko 131, Cramer, and Webster and would have had a reasonable expectation of success in doing so.

**(a) "Protrusion comprising a convex surface" ('502
claim 22, limitation [19C] from which claim 22
depends)**

The use of a protrusion with a convex surface was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Seiko 131 and Cramer. A POSITA would naturally look to these other devices to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination. RX-0411 at 7:58-63; Tr. [Warren] 1233:1-14; RDX-8.68 (summarizing RX-0411, RX-0666, RX-0670).

As discussed in Section IV.D.1.c.(1)(a), *supra*, Seiko 131 and Cramer both disclose this limitation. *E.g.*, RX-0666 at 3:22-28, 19:5-8, Fig. 28; RX-0670 at 5:45-51, Figs. 3 and 6; Tr. [Warren] 1232:15-1233:14; RDX-8.66-RDX-8.68 (summarizing RX-0411, RX-0666, RX-0670).

- (b) **“Separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes” and “the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue (’502 claim 22, limitation [19C] from which claim 22 depends)**

The use of openings positioned over photodiodes, including openings lined with opaque material to reduce unattenuated light, was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Seiko 131 and Cramer. A POSITA would naturally look to these other devices to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination. RX-0411 at 8:1-11; Tr. [Warren] 1234:10-21; RDX-8.71 (summarizing RX-0411, RX-0666, RX-0670).

As discussed in Section IV.D.1.c.(1)(b), *supra*, Seiko 131 and Cramer both disclose this limitation. *E.g.*, RX-0666 at Fig. 28; RX-0670 at 5:33-35, Fig. 6; RX-1221 at 1; Tr. [Warren] 1233:15-1234:21; RDX-8.69-RDX-8.71 (summarizing RX-0411, RX-0666, RX-0670).

- (c) **“Optically transparent material within each of the openings” (’502 claim 22, limitation [19C] from which claim 22 depends)**

The use of optically transparent materials within the openings over photodiodes was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, *e.g.*, Seiko 131, Cramer and Webster. A POSITA would naturally look to these other devices to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a

combination. RX-0411 at 8:19-26; Tr. [Warren] 1235:14-1236:2; RDX-8.74 (summarizing RX-0411, RX-0666, RX-0670, RX-1221).

As discussed in Section IV.D.1.c.(1)(c), *supra*, Seiko 131 and Cramer disclose these limitations. *E.g.*, RX-0666 at Fig. 28; RX-0670 at Fig. 6; RX-1221 at 1; Tr. [Warren] 1234:22-1236:2; RDX-8.72-RDX-8.74 (summarizing RX-0411, RX-0666, RX-0670, RX-1221).

(d) A “thermistor” and “one or more processors further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal” (502 claim 22, claims 20 and 21, from which claim 22 depends)

The use of thermistors to output temperature signals and processors to adjust operation based on signals from thermistors was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Webster. A POSITA would naturally look to Webster to improve on the disclosures of Lumidigm. Lumidigm expressly suggests such a combination including in its teaching of “performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature” and that “[t]hese and other techniques are well known in the art.” RX-0411 at 14:21-29, Fig. 9; Tr. [Warren] 1238:15-23, 1239:18-1240:3; RDX-8.81 (summarizing RX-0035, RX-0411).

As discussed in Section IV.D.1.c.(2), *supra*, Webster discloses these limitations. RX-0035 at 85, Fig. 3.4; Tr. [Warren] 1238:15-1240:3; RDX-8.79-RDX-8.81 (summarizing RX-0035, RX-0411).

(e) Motivation to Combine and Reasonable Expectation of Success

Lumidigm expressly suggests using each feature above in subsections (a) through (d), including the recited protrusion with a convex surface, openings over the photodiodes lined with

opaque material, transparent material within the openings, a thermistor, and processors to adjust operations based on signals from the thermistor. Lumidigm also expressly suggests that these all these features can be included in its wristwatch embodiment. RX-0411 at 11:60-12:2; *see also* Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4; Tr. [Rowe] at 1152:4-24.

As described in Sections IV.D.1.c.(1)(a)-(e), *supra*, a POSITA would have been motivated combine Lumidigm with Cramer, Seiko 131, as all are analogous art from the same field of light-based measurement devices, and would have had a reasonable expectation of success in doing so. A POSITA would have recognized the benefits of using a protrusion with a convex surface, the benefits of incorporating openings lined with opaque material over the photodiodes, and the benefits of including optically transparent material within each opening. Tr. [Warren] 1232:10-1236:2, 1237:4-1238:6, *see also* 1192:25-1195:22, 1210:13-1213:3.

Further, as described in Section IV.D.1.c.(2)(b), *supra*, a POSITA also would have been motivated to combine Lumidigm and Webster, as each is also from the same field of light-based measurement devices, and would have had a reasonable expectation of success in doing so. A POSITA also would have recognized the benefits of using a thermistor and a processor to compensate for temperature variations. Tr. [Warren] 1238:15-1240:3, *see also* 1223:1-20.

It would have been obvious to combine Lumidigm's wristwatch with Cramer's, Seiko 131's, and Webster's teachings for the same reasons, specifically combining the teachings would have amounted to nothing more than the use of a known technique to improve similar devices in the same way and the combining of prior art elements according to known methods to yield predictable results. As Professor Warren explained, "the three elements for the watch [i.e., Lumidigm, Seiko 131, and Cramer] all go together. It would be obvious then, as a person of ordinary skill in the art, to add the thermal sensing." Tr. [Warren] 1241:20-1242:9.

A POSITA would have been motivated to combine the teachings of Seiko 131, Cramer, and Webster, and to apply the combined teachings to Lumidigm's wristwatch. *Id.* A POSITA would recognize the various components of the device, including the protrusion with a convex surface, openings over the photodiodes lined with opaque material, thermistor, and processors to adjust operations based on signals from the thermistor above, could be used together and modified in accordance with good engineering principles and that a POSITA would have a reasonable expectation of success in making the modifications describe above and suggested in the references. *Id.* Lumidigm, Seiko 131, Cramer, and Webster are from the same field of endeavor and a POSITA would look to these types of references when considering design alternatives. Moreover, each feature and limitation in the claim has a known function and performs in the manner a POSITA would expect it to operate. This is equally true when multiple components of a design are brought together: each feature and component performs its known function in a known way and produces an expected result.

(4) Lumidigm in View of Webster and Apple '047 Render Obvious '502 claim 28

As referenced above, claim 28 of the '502 patent includes limitations reciting both a thermistor (limitation [28D]) and a user interface with a touch-screen display (limitation [28K]). For the reasons stated above, Lumidigm alone anticipates or renders obvious claim 28. In the alternative, Lumidigm in combination with Webster and Apple '047 render obvious claim 28.

U.S. Patent No. 9,001,047 ("Apple '047"), titled "Modal Change Based on Orientation of a Portable Multifunction Device," was filed January 4, 2008, issued April 7, 2015, and discloses a portable multifunction device with a touch screen user interface with modal and orientation change capability. RX-0673 [Apple '047] at Abstract. A POSITA would have been motivated to modify

Lumidigm based on the relevant teachings of Webster and Apple '047 and would have had a reasonable expectation of success in doing so.

- (a) **A “thermistor configured to provide a temperature signal” and, “the one or more processors further configured to receive the temperature signal” ('502 claim 28, limitations [28D] and [28I])**

As discussed in Section IV.D.1.c.(2), *supra*, in connection with '502 claims 20 and 21, the use of thermistors to output temperature signals and processors to receive those signals was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Webster. Tr. [Warren] 1238:18-23. A POSITA would naturally look to Webster to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination including in its discussion of “making corrections” based on temperature. RX-0411 at 14:21-29, Fig. 9; Tr. [Warren] 1223:1-20.

As discussed in Section IV.D.1.c.(2), *supra*, Webster discloses these limitations. RX-0035 at 85, Fig. 3.4; Tr. [Warren] 1238:15-1240:3; RDX-8.80 (summarizing RX-0035).

- (b) **A “user interface comprising a touch screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation of the user” ('502 claim 28, limitation [28K])**

The use of user interfaces with touch screen displays also was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Apple '047. A POSITA would have naturally looked to Apple '047 to improve on the disclosures of Lumidigm. Tr. [Warren] 1241:1-17. Lumidigm expressly suggests such a combination including in its teaching of a cellular telephone/PDA embodiment. RX-0411 at Figs. 8D-8E; RDX-8.47 (summarizing RX-0411). A POSITA would readily appreciate that Lumidigm's

wristwatch embodiment could also include a touch screen interface. RX-0411 at 3:35-37, 12:3-41, 12:56-63; Tr. [Warren] 1226:23-1227:7; RDX-8.47 (summarizing RX-0411).

By the time of the priority date of the Poeze Patents, Apple and others had already popularized the use of user interfaces with touch screens. *See* Tr. [Land] 955:10-956:4; Tr. [Warren] 1240:4-17. A POSITA would have been motivated to combine Lumidigm with Apple '047, including its teachings of the recited “network interface” for wireless communications to mobile phones, “touch screen,” and memory, and would have had a reasonable expectation of success in doing so. Tr. [Warren] 1241:1-17.

Apple '047 discloses the use of a touch screen display. The disclosed touch screen display has a portrait view and a landscape view and the view between portrait view and landscape view changes based on the orientation of the display. RX-0673 [Apple '047] at 3:17-20. Apple '047 also describes a touch sensitive display or touch screen: “FIGS. 1A and 1B are block diagrams illustrating portable multifunction devices 100 with touch-sensitive displays 112 in accordance with some embodiments. The touch-sensitive display 112 is sometimes called a ‘touch screen’ for convenience and may also be known as or called a touch-sensitive display system.” *Id.* at 5:65-6:3; Tr. [Warren] 1240:4-25; RDX-8.83 (summarizing RX-0673).

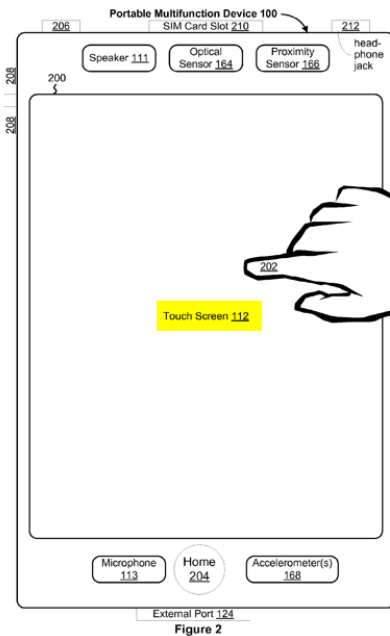


Figure 2

RX-0673 [Apple '047] at Fig. 2.

Apple '047 also describes the function of the touch screen where the “touch screen” has a touch sensitive surface that accepts input from a user based on tactile contact. A POSITA would have understood that the touch screen and the other elements disclosed by Apple '047 could have readily been combined with Lumidigm and would have yielded predictable results in doing so. Tr. [Warren] 1226:23-1227:7, 1240:4-1241:14; RDX-8.84 (summarizing RX-0411, RX-0035, RX-0673).

A POSITA would have been motivated to combine Lumidigm's wristwatch with these teachings from Apple '047 because (1) Lumidigm expressly discloses touch screen displays, including to display indicia responsive to a user's oxygen saturation (RX-0411 at Figs. 8B-8E, 3:35-37, 21:29-36); and (2) a POSITA would have independently looked to literature like Apple '047 for this element as the benefits were well-known and in fact, Apple '047 states these benefits and suggests including this feature. RX-0673 at 5:64-6:3, Fig. 2; Tr. [Warren] 1226:23-1227:3,

1240:4-1242:9; RDX-8.83-RDX-8.85 (summarizing RX-0035, RX-0411, RX-0666, RX-0670, RX-0673).

**(c) Motivation to Combine and Reasonable
Expectation of Success**

Lumidigm expressly suggests using each feature above in subsections (a) and (b), including a thermistor configured to provide a temperature signal, processors configured to receive the temperature signal, and a user interface with a touch screen display configured to display indicia responsive to an oxygen saturation measurement of a user. It also expressly suggests that all these features can be included in its wristwatch embodiment. RX-0411 at 11:60-12:2. Additionally, each element was well known and taught in many prior art references, and a POSITA would have known that the elements could have been combined to yield predictable results. Tr. [Warren] 1223:1-20, 1226:23-1227:7, 1238:15-1241:17. A POSITA would have been motivated to look at Webster and Apple '047 as each are analogous art from the same field of light-based measurement devices. *Id.*

As discussed in Section IV.D.1.c.(2), *supra*, a POSITA would have been motivated to combine Lumidigm and Webster and would have had a reasonable expectation of success in doing so. A POSITA also would have recognized the benefits of incorporating temperature measurement using a thermistor and would have recognized that temperature sensing with a thermistor was a well-known mechanism for making corrections based on temperature. Tr. [Warren] 1238:15-1239:8, *see also* 1223:1-20.

A POSITA would also have found it obvious to use a touch screen display as a user interface as disclosed in Apple '047 with the physiologic measuring device described in Lumidigm. Tr. [Warren] 1241:1-17. Specifically, a POSITA would have known of the widespread availability of touch screens as user interfaces. *Id.* at 1226:23-1227:3, 1240:4-17.

Such an application of known touch screen technology that has a known usefulness would have been implemented in a predictable manner with an expected result in a device for measuring a physiologic parameter. *Id.* at 1226:23-1227:3, 1240:4-17, 1241:1-17.

Apple filed its first patent applications on touch screen technology long before the filing of the Asserted Poeze Patents, and Apple has been at the forefront of developing and promoting touch screen technology. It would have been obvious to combine these teachings and other teachings of touch screens, including for example, RX-0035 at 114, 137, and 218-223 and RX-0673 [Apple '047], because the combination would have provided an improved user experience and lower costs, and a POSITA would have had a reasonable expectation of success in doing so. *See* Tr. [Warren] 1241:1-17.

A POSITA would have also known that touch screens would be a suitable way to display indicia responsive to the measurement of the physiologic parameter. Touch screens were well known and used in a variety of personal devices including cell phones (*e.g.*, iPhone in 2007). A POSITA would have further understood that touch screens could be used on user-worn devices, like watches. RX-0411 at 11:60-12:2; *see also* Tr. [Warren] 1226:23-1227:7, *see also* 1204:18-1206:7, 1208:1-13, 1214:12-1215:4; Tr. [Rowe] at 1152:4-24.

A POSITA would have had a reasonable expectation of success when using a touch screen to display indicia responsive to a measurement of a physiologic parameter on a user-worn device. Additionally, a POSITA would understand that the display of a physiologic parameter on a touch screen of a user-worn device would have been sensible to achieve the form/function desired in the device.

A POSITA would have combined the teachings of Lumidigm, Webster, and Apple '047 as doing so would have amounted to nothing more than the use of a known technique to improve

similar devices in the same way and the combining of prior art elements according to known methods to yield predictable results. Tr. [Warren] 1226:23-1227:7, 1238:15-1241:17; RDX-8.84 (summarizing RX-0035, RX-0411, RX-0673). A POSITA would be motivated to combine the teachings of Webster and Apple '047 and to apply teachings to Lumidigm. *Id.* A POSITA would recognize that various components of the device such as thermistors and touch screens could be used together and modified in accordance with good engineering principles and that a POSITA would have a reasonable expectation of success in making the modifications describe above and suggested in the references. *Id.* Moreover, each feature and limitation in the claim has a known function and performs in the manner a POSITA would expect it to operate. *Id.* This is equally true when multiple components of a design are brought together: each feature and component performs its known function in a known way and produces an expected result. *Id.*

(5) Lumidigm in View of Seiko 131, Cramer, Webster, and Apple '047 Render Obvious '502 Claim 28

In addition to combining Lumidigm with Webster and Apple '047 *alone* for purposes of '502 claim 28, it also would have been obvious to combine Lumidigm with Seiko 131, Cramer, Webster, and Apple '047. Seiko 131 and Cramer teach the recited protrusion with a convex surface, openings defined by opaque surfaces, and transmissive windows ([limitations [28E], [28F], [28G]], Webster teaches the recited thermistor (limitation [28D]), and Apple '047 teaches the recited user interface with a touch screen (limitation [28K]). A POSITA would have been motivated to modify Lumidigm's wristwatch based on the relevant teachings of Seiko 131, Cramer, Webster, and Apple '047, and would have had a reasonable expectation of success in doing so. Tr. [Warren] 1241:18-1242:9; RDX-8.85 (summarizing RX-0035, RX-0411, RX-0666, RX-0670, RX-0673).

(a) “Protrusion comprising a convex surface” (’502 claim 28, limitation [28E])

The use of a protrusion with a convex surface was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Seiko 131 and Cramer. *E.g.*, RX-0411 at 7:58-63; Tr. [Warren] 1233:1-14; RDX-8.68 (summarizing RX-0411, RX-0666, RX-0670).

As discussed in Section IV.D.1.c.(1)(a), *supra*, Seiko 131 and Cramer both disclose this limitation. *E.g.*, RX-0666 at 3:22-28, 19:5-8, Fig. 28; RX-0670 at 5:45-51, Figs. 3 and 6; Tr. [Warren] 1232:15-1233:14; RDX-8.66-RDX-8.68 (summarizing RX-0411, RX-0666, RX-0670).

(b) A “plurality of openings in the convex surface, extending through the protrusion and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping” (’502 claim 28, limitation [28F])

The use of openings through a convex protrusion and aligned over photodiodes where the openings are defined by an opaque surface to reduce light piping was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Seiko 131 and Cramer. A POSITA would naturally look to these other devices to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination. RX-0411 at 8:1-11; Tr. [Warren] 1234:9-21; RDX-8.71 (summarizing RX-0411, RX-0666, RX-0670).

As discussed in Section IV.D.1.c.(1)(b), *supra*, Seiko 131 and Cramer both disclose this limitation. *E.g.*, RX-0666 at Fig. 28; RX-0670 at 5:33-35, Fig. 6; RX-1221 at 1; Tr. [Warren] 1233:15-1234:21; RDX-8.69-RDX-8.71 (summarizing RX-0411, RX-0666, RX-0670).

(c) A “plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings” (’502 claim 28, limitation [28G])

The use of transmissive windows extending across openings over photodiodes was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Seiko 131 and Cramer. A POSITA would naturally look to these other devices to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination. RX-0411 at 8:19-26; Tr. [Warren] 1235:13-1236:2; RDX-8.74 (summarizing RX-0411, RX-0666, RX-0670, RX-1221).

As discussed in Section IV.D.1.c.(1)(c), *supra*, Seiko 131 and Cramer disclose this limitation. *E.g.*, RX-0666 at Fig. 28; RX-0670 at Fig. 6; RX-1221 at 1; Tr. [Warren] 1234:22-1236:2; RDX-8.72-RDX-8.74 (summarizing RX-0411, RX-0666, RX-0670, RX-1221).

(d) A “thermistor configured to provide a temperature signal” and, “the one or more processors further configured to receive the temperature signal” (502 claim 28, limitations [28D] and [28I])

The use of thermistors to output temperature signals and processors to adjust operation based on signals from thermistors was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Webster. A POSITA would naturally look to Webster to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination. RX-0411 at 14:21-29, Fig. 9; Tr. [Warren] 1223:1-20.

As discussed in Section IV.D.1.c.(2), *supra*, Webster discloses these limitations. RX-0035 at 85, Fig. 3.4; Tr. [Warren] 1238:15-1240:3; RDX-8.80 (summarizing RX-0035).

- (e) A “user interface comprising a touch screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation of the user” (’502 claim 28, limitation[28K])

The use of user interfaces with touch screen displays also was well known in the art at the time the Poeze Patents were filed and was disclosed in multiple references including, for example, Apple ’047. A POSITA would naturally look to these other devices to improve on the disclosures of Lumidigm, and Lumidigm expressly suggests such a combination. RX-0411 at Figs. 8D-8E’ Tr. [Warren] 1226:23-1227:7, 1240:4-1241:17; RDX-8.47 (summarizing RX-0411).

As discussed in Section IV.D.1.c.(4), *supra*, Apple ’047 discloses this limitation. RX-0673 [Apple ’047] at 5:64-6:3, Fig. 2; Tr. [Warren] 1240:4-25; RDX-8.83 (summarizing RX-0673).

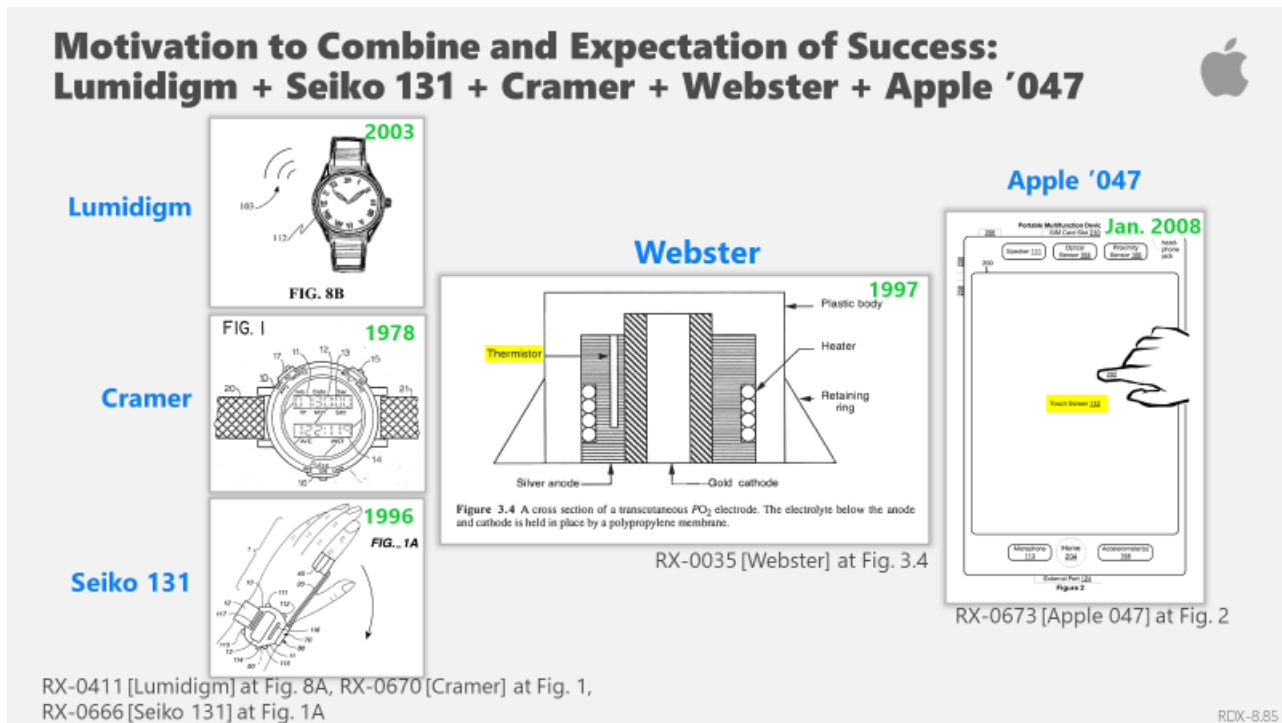
(f) **Motivation to Combine and Reasonable Expectation of Success**

Lumidigm expressly suggests using each feature above, including the recited protrusion with a convex surface, openings defined by an opaque surface to reduce light piping, transmissive windows, thermistor, and a user interface with a touch screen display. It also expressly suggests that all these features can be included in its wristwatch embodiment. RX-0411 at 11:60-12:2. Additionally, each element was well known and taught in many prior art references, and a POSITA would have known that the elements could have been combined to yield predictable results. Tr. [Warren] 1226:23-1227:7, 1232:10-1236:2, 1237:4-1242:9, *see also* 1192:25-1195:22, 1203:6-9, 1210:13-1213:3. A POSITA would have been motivated to look at Cramer, Seiko 131, Webster, and Apple ’047 as each is analogous art from the same field of light-based measurement devices. *Id.* It would have been obvious to a POSITA to look to devices that measure physiological parameters, e.g., pulse rate and blood oxygen, as all make use of the same general components and techniques. *Id.*

As discussed in Section IV.D.1.c.(3), *supra*, a POSITA would have been motivated to combine the teachings of Lumidigm with Seiko 131, Cramer, and Webster, and would have had a reasonable expectation of success in doing so. A POSITA also would have recognized the benefits of using a protrusion with a convex surface, the benefits of incorporating openings over the photodiodes with opaque surfaces to reduce light piping, the benefits of including transmissive windows over the openings, and the benefits of including a thermistor to provide a temperature signal and processors to receive and use that signal. *See* Tr. [Warren] 1232:10-1240:3, *see also* 1192:25-1195:22, 1210:13-1213:3.

Additionally, as discussed in Section IV.D.1.c.(4), *supra*, a POSITA also would have been motivated to combine Lumidigm with Webster and Apple '047, and would have had a reasonable expectation of success in doing so. A POSITA also would have recognized the benefits of using a user interface with a touch screen display configured to display indicia responsive to an oxygen saturation measurement of a user. *See* Tr. [Warren] 1226:23-1227:7, 1240:4-1242:9.

It would have been obvious to combine the teachings of Seiko 131, Cramer, Webster, and Apple '047, and apply those combined teachings to Lumidigm's wristwatch, for the same reasons, as combining the teachings would have amounted to nothing more than the use of a known technique to improve similar devices in the same way and the combining of prior art elements according to known methods to yield predictable results. Tr. [Warren] 1226:23-1227:7, 1232:10-1236:2, 1237:4-1242:9. Again, "the three elements for the watch [i.e., Lumidigm, Seiko 131, and Cramer] all go together. It would be obvious then, as a person of ordinary skill in the art, to add the thermal sensing and the touchscreen elements via Webster or Apple or any number of other references to accomplish this":



Tr. [Warren] 1241:18-1242:9; RDX-8.85 (summarizing RX0411, RX-0666, RX-0670, RX0035, RX-0673).

A POSITA would be motivated to combine the teachings of Seiko 131, Cramer, Webster, and Apple '047 and to apply these teachings to Lumidigm's wristwatch. Specifically, Lumidigm, Seiko 131, and Cramer are all wrist-worn embodiments of a physiological sensor, and therefore the addition of well-known concepts of a thermistor and touchscreen is effectively a combination of three references (Lumidigm, Seiko 131, and Cramer), plus one (Webster), plus one (Apple '047). Tr. [Warren] 1241:18-1242:9.

A POSITA would recognize that various components of the device, including a protrusion with a convex surface, openings over the photodiodes defined by an opaque surface, transmissive windows extending over the openings, a thermistor, processors to adjust operations based on signals from the thermistor, and a user interface with a touch screen, could be used together and modified in accordance with good engineering principles, and a POSITA would have a reasonable

expectation of success in making the modifications describe above and suggested in the references. Tr. [Warren] 1232:10-1242:9. Moreover, each feature and limitation in the claim has a known function and performs in the manner a POSITA would expect it to operate. *Id.* This is equally true when multiple components of a design are brought together: each feature and component performs its known function in a known way and produces an expected result. *Id.*

d. No Secondary Considerations of Non-Obviousness

Complainants failed to demonstrate the existence of any secondary considerations that could support a finding of non-obviousness. There are none.

No copying. Complainants have shown no evidence of copying of the Poeze Patents by Apple. Tr. [Warren] 1246:13-16; Tr. [Kiani] 134:9-137:7 (admitting no direct evidence of copying or misuse of information by Apple). Nor could they. Apple Watch Series 6 with the Blood Oxygen feature accused in this case was released *before* Complainants applied for the Poeze Patents; Apple therefore could not have copied the features recited in the claims themselves. JX-001-JX-003; RX-0333 [September 15, 2020 Apple press release announcing Apple Watch Series 6]. Nor could Apple have copied the Masimo Watch—the only Masimo product Complainants have alleged practice those patents—since images of that watch were not even made public until **2022** and the device itself is still not available to the general public. CX-0778C [Photographs of W1 from Arab Health in January 2022]; Tr. [Muhsin] 353:24-354:9 (confirming Complainants “debuted the W1 at Arab Health” in January 2022).

That Masimo has no evidence of copying is unsurprising. As all of Apple’s engineers testified, they developed the accused Blood Oxygen feature through their own hard work and innovation, and not by copying Masimo or any other company’s technology. *E.g.*, Tr. [Block] 902:10-12 (“Did you copy any other company’s technology when developing the blood oxygen

“light piping” or how to “avoid” or “reduce” light piping, aside from general references to the use of opaque materials. Tr. [Warren] 1247:24-1248:4 (“Q. ... [H]ave you seen anything in the Poeze specification that provides guidance on reducing or avoiding light piping other than a general reference to the use of opaque materials? A. No. I’ve just seen a vague correlation between the two, that’s it.”). The specification also does not explain when “light piping” has been “substantially” prevented, or how the inventors accomplish this with “a protrusion compris[ing] opaque material configured to substantially prevent light piping.” *Id.* The specification suggests, at a high level, that opaque material may help reduce noise including “light piping” but offers no teachings enabling others to accomplish the same goal and no guidance on the circumstances under which a POSITA can determine if it has been “substantially prevent[ed].” JX-002 [’502 patent] at 7:65-8:7. The specification also provides no written description of how the inventors constructed their sensor to accomplish this. In rebuttal, Dr. Madisetti merely identified instances in which the specification discusses reduction of light piping (Tr. [Madisetti] 1350:4-21, 1352:25-1353:11), but never explained how those threadbare disclosures would enable a POSITA to “reduce” or “avoid” light piping as required by the claims, or how the specification provides guidance on when such light piping has been “substantially” prevented. For these reasons, these three claims are valid for lack of enablement, and ’648 claim 24 is further invalid for lack of written description.

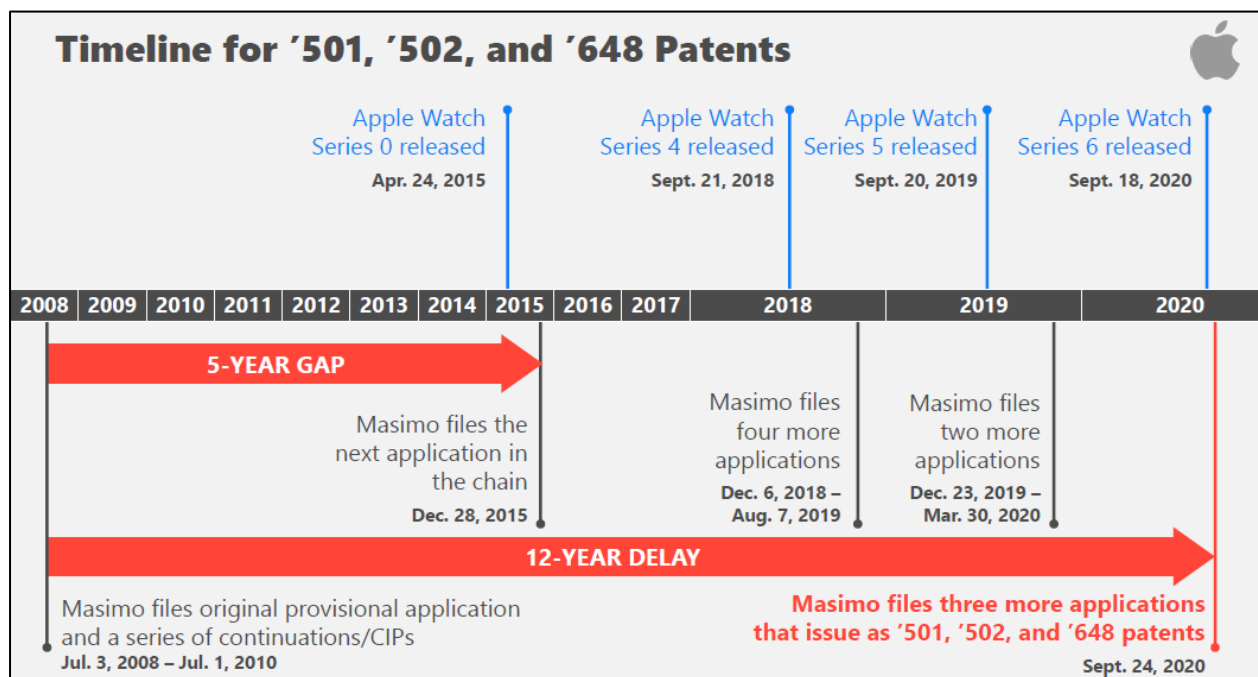
E. Unenforceability

1. Prosecution Laches

The Poeze Patents are unenforceable under the doctrine of prosecution laches because Masimo unreasonably and inexcusably delayed prosecuting them, causing Apple material prejudice. *Cancer Research. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728-29 (Fed. Cir. 2010).

Between July 3, 2008 and August 25, 2008, Masimo filed seven original provisional applications to which the Poeze Patents claim priority. JX-001.3 ['501 patent] (paragraph (60)); *accord* JX-002.2 ['502 patent]; JX-003.3 ['648 patent]. Soon thereafter, on August 25, 2008, Masimo filed two related design patents. JX-001.3 ['501 patent] (paragraph (60)); *accord* JX-002.2 ['502 patent]; JX-003.3 ['648 patent]. Masimo continued to file related continuations and continuations-in-part until July 1, 2010. JX-001.3 ['501 patent] (paragraph (60)); *accord* JX-002.2 ['502 patent]; JX-003.3 ['648 patent].

After this concentrated succession of applications in this patent family, Masimo put a hold on any new applications in this family for nearly five years—resuming only after Apple launched Apple Watch. Masimo then embarked on a pattern of filing new applications shortly after the release of new Apple Watch series:



[REDACTED]

[REDACTED]

RDX-1.16 (based on CX-1287.10; CX-1532.11-12; RX-0333.0011; RX-0023.0001; JX-001.3 [’501 patent] (paragraph (60)); JX-002.2 [’502 patent]; JX-003.3 [’648 patent]); *see also* Tr. [Kiani] 138:1-10 (acknowledging Apple Watch release dates).

On September 18, 2020, Apple released Apple Watch Series 6—the first of the Accused Apple Watches. CX-1287.10; *accord* CX-1532.11-12; RX-0333.0011. Days later, on September 24, 2020, Masimo filed three continuation patents applications that ultimately issued as the Poeze Patents, in early 2021. JX-001.2 [’501 patent] (paragraph (62)); *accord* JX-002.1 [’502 patent]; JX-003.2 [’648 patent]; *see also* Tr. [Cromar] 1030:18-1031:6. In other words, it was not until *after* Apple’s release of Series 6 Watch in September 2020—more than *twelve years* after the initial application to which those patents claim priority—that Masimo filed the applications for the Poeze Patents. While “[t]here are no ‘firm guidelines’ for when laches is triggered ... the Federal Circuit has found instructive two prior Supreme Court cases finding ‘patents unenforceable based on eight and nine-year prosecution delays.’” *Personalized Media Commc’ns, LLC v. Apple, Inc.*, 552 F. Supp.3d 664, 686 (E.D. Tex. 2021) (No. 2:15-CV-01366-JRG, 2021 WL 3471180, at *16 (E.D. Tex. Aug. 5, 2021) (quoting *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 422 F.3d 1378, 1385 (Fed. Cir. 2005); *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1366-37 (Fed. Cir. 2021) (citations omitted)).

Masimo attempted to show that its prosecution of earlier filed applications in the Poeze Patent family was diligent, but made no effort to explain why it waited more than twelve years to *file* the asserted Poeze Patents, thereby significantly delaying the prosecution of those patents specifically. That is, prosecution activities with respect to other applications cannot justify the unreasonable delay *for the asserted patents*. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See Tr. [Cromar] 1029:12-1030:17 [REDACTED]

[REDACTED] Tr. [Kiani] 153:16-23 [REDACTED]

[REDACTED]. Although Mr. Cromar incorrectly suggested the timeline above is “missing some of the filings” (Tr. 1038:10-19), the prosecution histories speak for themselves: After a concentrated period of applications between July 2008 and July 2010 (noted on the timeline) Masimo waited five years before filing any additional new applications (after Series 0 was released); and waited twelve years after the original provisionals to file the applications for the Poeze Patents. JX-001.2-3 [’501 patent]; JX-002.1-2 [’502 patent]; JX-003.2-3 [’648 patent]. It is irrelevant whether “there was active prosecution through that time period” of *other* patents in the family (Tr. [Cromar] 1036:11-18); the relevant inquiry is whether the delay in filing the *asserted* patents is unreasonable. It was.

Complainants’ patent-prosecution expert, Robert Stoll, similarly testified that the prosecution of members of the Poeze Patent family proceeded at an ordinary pace, with specific reference to prosecution activity for three applications in that family. Tr. [Stoll] 1410:23-1411:7 (discussing CDX-0016C.002). Again, Mr. Stoll offered no opinions with respect to the timing of the *filing* of the *specific* applications that resulted in the ’501, ’502, and ’648 patents—which, according to both Masimo’s prosecution counsel and CEO, could have been filed at any point after 2008, but were not filed until twelve years later and *after* the launch of the first accused product.

The totality of the circumstances, including the series of events from 2008 to 2020, shows that Masimo lacked diligence in filing and prosecuting the Poeze Patents. Instead, by apparently tying its filings and prosecutions of its continuation applications to Apple’s product releases, the

most reasonable inference is that Masimo intentionally and methodically delayed prosecution to allow the market for wearable technology to grow and gain the benefit of being able to draft claims following Apple's releases of its new products in that market. The fact that Masimo's delays were not isolated, but instead tracked the releases of Apple Watch products, strongly suggests that Masimo inexcusably delayed its patents. *See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research. Found.*, 422 F.3d 1378, 1385-86 (Fed. Cir. 2005) (noting that "prosecution laches may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution" and that "an examination of the totality of the circumstances, including the prosecution history of all of a series of related patents and overall delay in issuing claims, may trigger laches")

Furthermore, Apple has suffered prejudice due to Masimo's misconduct. During the time between Masimo's original provisional applications and filing of the Poeze Patents, Apple invested heavily in developing Apple Watch, improving on the technology from generation to generation, and helping grow the wearable technology market.²⁵ *See, e.g., Seaboard Int'l, Inc. v. Cameron Int'l Corp.*, No. 1:13-CV-00281-MLH-SKO, 2013 WL 3936889, at *4 (E.D. Cal. July 30, 2013) (allegations of investments made in accused product during delay in prosecution sufficient to state claim for prosecution laches). By delaying its filing of the Poeze Patents until Apple had already released the Series 6, Masimo also gained an improper litigation advantage by drafting claims

²⁵ *See, e.g.,* Tr. [Waydo] 923:1-926:6, 933:12-934:10 (Apple's Director of Human Interface Devices Health describing efforts to develop blood-oxygen feature, including [REDACTED] *id.* 926:1-6, as well as Apple's general approach to technology development); Tr. [Land] 954:23-955:9, 957:5-959:2, 962:15-966:7 (describing health-sensing-hardware group of [REDACTED] as well as efforts to develop blood-oxygen feature); *see also* RX-0094C ([REDACTED] of Apple Watch Series 6 hardware); RX-0023, CX-1287, CX-1532, RX-0333 (Apple Watch press releases).

intended to cover those products. *See In re Bogese*, 303 F.3d 1362, 1369 (Fed. Cir. 2002) (rejecting argument that delay in prosecution was justified by patentee’s desire to obtain claims on competitive products); *Hynix Semiconductor Inc. v. Rambus Inc.*, Nos. CV-00-20905-RMW, C-05-02298 RMW, C-05-00334 RMW, C-06-00244 RMW, 2007 WL 4209386, at *4-5 (N.D. Cal. Nov. 26, 2007) (denying summary judgment on prosecution laches, noting in part that “[i]nternal Rambus documents also strongly suggest that Rambus was drafting its claims to cover technologies as they developed”). [REDACTED]

[REDACTED]

[REDACTED] But for Masimo’s bad-faith actions in delaying prosecution of its patents, it would not currently be in position to bring this action against Apple.

2. Unclean Hands

Complainants’ actions during prosecution of the Poeze Patents discussed in Section IV.E.1, *supra*, further warrant that their claims for relief with respect to those patents be barred under the doctrine of unclean hands. “[A] determination of unclean hands may be reached when ‘misconduct’ of a party seeking relief ‘has immediate and necessary relation to the equity that the seeks in respect of the matter in litigations,’ i.e. ‘for such violation of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court.’” *Gilead Scis., Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 797 (2019) (*quoting Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933)). “The ‘immediate and necessary relation’ standard, in its natural meaning, generally must be met if the conduct normally would enhance the claimant’s position regarding

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**

**Before the Honorable Monica Bhattacharyya
Administrative Law Judge**

**In the Matter of
CERTAIN LIGHT-BASED PHYSIOLOGICAL
MEASUREMENT DEVICES AND
COMPONENTS THEREOF**

Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S CORRECTED REPLY POST-HEARING BRIEF

To begin with, the Poeze Patents include *no* teachings whatsoever on taking a measurement on a wrist. Instead, all of the examples in the Poeze Patents are traditional, finger-based sensors. RIB 8 (citing Tr. [Warren] 1200:23-1201:13; JX-001 [’501 patent]). Moreover, although the wrist poses more complications than other measurements sites, Professor Warren’s own *undergraduate* students were building pulse oximeters that could take measurements on a wrist *six years* before the Poeze priority date. *See* RX-0632 [2002 photograph].

Complainants also cannot rebut Apple’s demonstration of invalidity under Section 112, based on Complainants’ filing of claims that stretched too far beyond the written-description support or enablement offered by the specification.

Second, the claims did not stretch far enough, and Complainants fail to rebut the detailed noninfringement positions that Apple presented at the evidentiary hearing. Complainants mischaracterize or ignore key evidence demonstrating noninfringement of the Poeze Patents. There is *no* dispute that the Accused Apple Watches cannot take blood-oxygen measurements when face-down, and there is *no* dispute that the [REDACTED]

[REDACTED]. Based on the plain and ordinary meaning of the asserted claims, therefore, the Accused Apple Watches are not configured to take blood-oxygen readings when the accused openings and protrusion are “*over*” or “*above*” the interior surface and photodiodes, nor are there any openings or holes that extend “*through*” as the claims require. Rather than addressing these arguments directly, Complainants instead advance new claim-

construction positions⁴ that rely on the baseless opinions of Dr. Madisetti,⁵ unpersuasively arguing that Apple’s plain-meaning arguments should be rejected.

Third, Complainants have failed to carry their burden of demonstrating that any of the “Masimo Watch” devices practices any claim of the Poeze Patents, as they must under the technical prong of the domestic-industry requirement. Out of frustration with the pace of their district-court litigation against Apple, Complainants launched their complaint far too early in the design process for their domestic-industry devices, which even as of the time of the evidentiary hearing were not available for purchase on the open market. The mishmash of evidence in the record, from both before and after the filing of the Complaint, cannot suffice to show that Complainants have created any practicing article capable of taking physiological measurements—much less that Complainants have created a meaningful domestic industry.

Finally, Complainants fail to provide any compelling explanation for the extraordinary delay in the prosecution of the asserted claims until *after* the release of the first accused Apple Watch, which supports a finding of unenforceability due to prosecution laches.

A. Noninfringement

Complainants have long known of Apple’s noninfringement arguments for the Poeze Patents, namely, that (1) the Accused Apple Watches are configured not to measure blood oxygen

⁴ As discussed further below, many of the arguments in Complainants’ initial post-hearing brief, both for non-infringement and other merits issues concerning the Poeze Patents (and the other Asserted Patents), were not presented in their pre-hearing brief or at the evidentiary hearing and are therefore waived. G.R. 13.1.

⁵ As noted in Apple’s initial post-hearing brief, there is no reason that any opinion of Dr. Madisetti should be credited. Dr. Madisetti is a professional expert who has testified against Apple in numerous proceedings involving a vast range of technologies. His direct testimony in this Investigation consisted primarily of reading virtually verbatim the text on his demonstratives as though those slides were a script. His testimony on cross examination revealed an understanding of the operation of Apple Watch that was, stating it generously, incomplete and uncertain. RIB 24-26.

when face-down (*i.e.*, the alleged protrusion is “over” or “above” the photodiodes), and (2) the [REDACTED] such that there are no openings extending *through* the accused protrusion in the final product. Unable to dispute the facts, Complainants instead advance claim constructions to read out these limitations—while ironically suggesting that *Apple* has raised “new constructions.” The ALJ should reject Complainants’ attempts to deviate from the plain meaning of the claims, under which there is no infringement.

1. Apple’s Noninfringement Arguments Apply Plain Meaning.

The ALJ has already rejected Complainants’ contention that Apple’s argument and Professor Warren’s opinions regarding why the Accused Apple Watches do not satisfy the “over”/“above” and “openings” limitations are untimely claim constructions. *See* Order No. 36 at 3 (June 1, 2022) (Doc. ID 772014) (“Apple complied with the Ground Rules by disclosing its positions with respect to the *plain and ordinary meaning of these terms* in its final non-infringement contentions. ... Dr. Warren’s opinions regarding the terms ‘over’ and ‘opening’ will not be excluded from the hearing.”). Consistent with this ruling, Apple and Professor Warren presented arguments based on the plain meaning of those terms. Complainants’ attempt to prove infringement by rewriting their claims at the eleventh hour should be rejected.

2. No Protrusions, Openings, or Through Holes “Over” or “Above” Interior Surface or Photodiodes When Configured to Measure Physiological Parameter (’501 Claim 12; ’502 Claims 22 and 28; and ’648 Claims 24, 30)

a. The Accused Apple Watches Do Not Infringe.

The Accused Apple Watches do not infringe because they can *never* satisfy all limitations. RIB 26-34; *Engel Indus. v. Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996) (“Literal infringement of a claim exists when every limitation recited in the claim is found in the accused

device....”). Complainants do not dispute that Apple Watch *cannot* take a blood-oxygen measurement when face-down, nor could they. Complainants claim it is undisputed that the Accused Apple Watches are “configured to noninvasively measure blood oxygen saturation” (CIB 59-60) and include processors and software that “calculates, determines, and outputs measurements indicative of the average SpO2” (CIB 64-65).⁶ But the same documents Complainants rely on for these limitations confirm that the Accused Apple Watches are “configured to” do so *only* when face down—*i.e.*, when the alleged protrusion is *under* the photodiodes. *E.g.*, CIB 60 (citing, for example, CX-1406 (which instructs at p.2 to “...make sure your wrist is flat, with the Apple Watch display facing up...” at 2) and CX-0100C [REDACTED]

see also RIB 28-31.

Unable to dispute the facts, Complainants deflect with unsubstantiated accusations that Apple “fabricated” its noninfringement position through “contrived testimony” of its engineers. CIB 56. But the testimony of Apple’s engineers—including the cited testimony of Dr. Venugopal—is truthful and consistent with contemporaneous documents. Complainants’ alleged evidence to the contrary consists of Apple patents (which as discussed below are consistent with Apple’s positions in this case) and a passing reference in an Apple development document to [REDACTED] *Id.* (citing CX-0011C.26).⁷ This reference, on its face, relates to the unrelated

⁶ Complainants also suggest the Accused Apple Watches satisfy the preambles because they are configured to measure pulse rate. CIB 59. But Dr. Madisetti did not discuss pulse rate in his analysis for the preambles and mentioned “pulse rate” in Apple Watch only in the context of the blood-oxygen algorithm—not as a separate measurement. Tr. [Madisetti] 679:10-680:5, 685:4-13, 689:17-690:16.

⁷ Complainants did not identify this disclosure of CX-0011C in their pre-hearing brief or during the hearing; this argument is waived.

[REDACTED], and it does not contradict any evidence showing that the [REDACTED] feature will not work face down.

Complainants also incorrectly argue that *Nazomi Communications, Inc. v. Nokia Corp.*, 739 F.3d 1339 (Fed. Cir. 2014), does not bear on this case because “Apple configures the Accused Products to noninvasively measure and calculate oxygen saturation.” CIB 56-57. In *Nazomi*, the Federal Circuit reiterated that a product does not infringe an apparatus claim if the product must be modified to practice that claim, explaining that a software change amounts to a modification precluding infringement. 739 F.3d at 1345-46. As is undisputed, the software on the Accused Apple Watches prevents blood-oxygen readings when Watch is face-down. To support face-down readings, the software would need to be altered—precluding infringement under *Nazomi*.

For these reasons and those set out in Apple’s Post-Hearing Brief, the Accused Apple Watches do not infringe claims 12 of the ’501 patent, 22 and 28 of the ’502 patent, or 24 and 30 of the ’628 patent. RIB 26-34.⁹

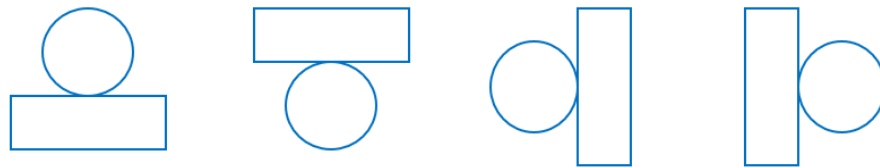
b. Complainants’ Claim Construction Arguments Are Wrong.

Unable to show that the Accused Apple Watches can, at any time, satisfy all limitations, Complainants construe “over” and “above” to render those words meaningless. Complainants’ new claim construction positions are untimely, and wrong in any event. *See Conoco, Inc. v. Energy*

⁸ [REDACTED] Tr. [Land] 965:9-11.

⁹ Complainants argue that Apple waived its “over” arguments for the “through holes” in ’648 patent claims 24 and 30 due to alleged nondisclosure in contentions. CIB 81 nn.7-8. This argument is both wrong and untimely; Apple advanced the “over” argument for these claims in its pre-hearing brief and in Professor Warren’s testimony, and Complainants did not object or move to strike. RPHB 8-11; Tr. [Warren] 1249:8-1252:6; *see also* CX-1251C.218 (contention that “Complainants have failed to demonstrate that the Accused Products possess ‘a protrusion’ with ‘through holes ... arranged over’ photodiodes as required by [’648 patent] claim 20,” from which claims 24 and 30 depend).

& *Env'tl. Int'l, L.C.*, 460 F.3d 1349, 1358-1359 (Fed. Cir. 2006) (“[L]itigants waive their right to present new claim construction disputes if they are raised for the first time after trial.”). Complainants argue that the “over” and “above” language merely “refers to the configuration of *features of the device relative to each other*, not to the position of the device.” CIB 43 (citing JX-0001 Figs. 3C, 3E, 4C, 7B).¹⁰ But what Complainants imply is that *any* relative orientation would satisfy this requirement. Under Complainants’ interpretation, the rectangle would be “above” or “over” the circle in any of the following configurations:



This contravenes the rule that *every* word in the claim matters. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”).¹¹

Beyond the problem that Complainants’ construction would render the terms “over” and “above” meaningless, it also has no evidentiary support. *First*, the specification supports Apple’s understanding of the plain meaning of these terms. In each cited figure—and every other embodiment—the protrusion and openings are spatially positioned on top of, or higher than, the photodiodes, consistent with the plain meaning of “above” and “over”:

¹⁰ In their initial pre-hearing brief and at the hearing, Complainants did not raise this argument as to at least Figures 3C, 3E, and 4C; such arguments are waived. *See* CPHB 39-41.

¹¹ In passing, Complainants suggest yet another construction: “The claim itself ... specifies the position of ‘over’ by reciting that the protrusion *covers* multiple photodiodes and contacts the user’s skin.” CIB 43. But “cover” is not in the claims, nor do Complainants allege this alternative interpretation is supported by the specification (and it is not).

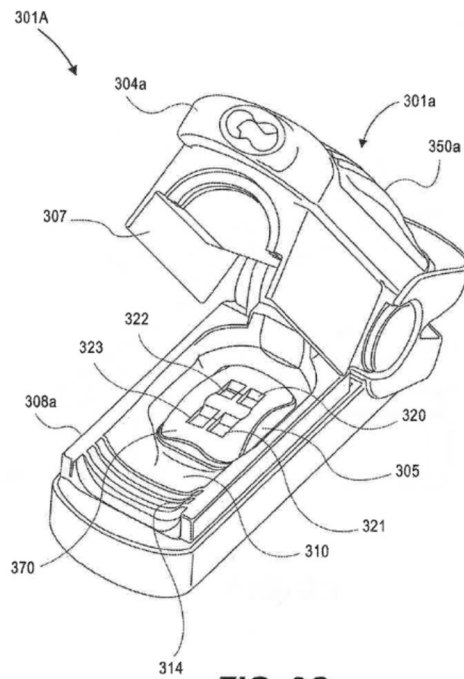


FIG. 3C

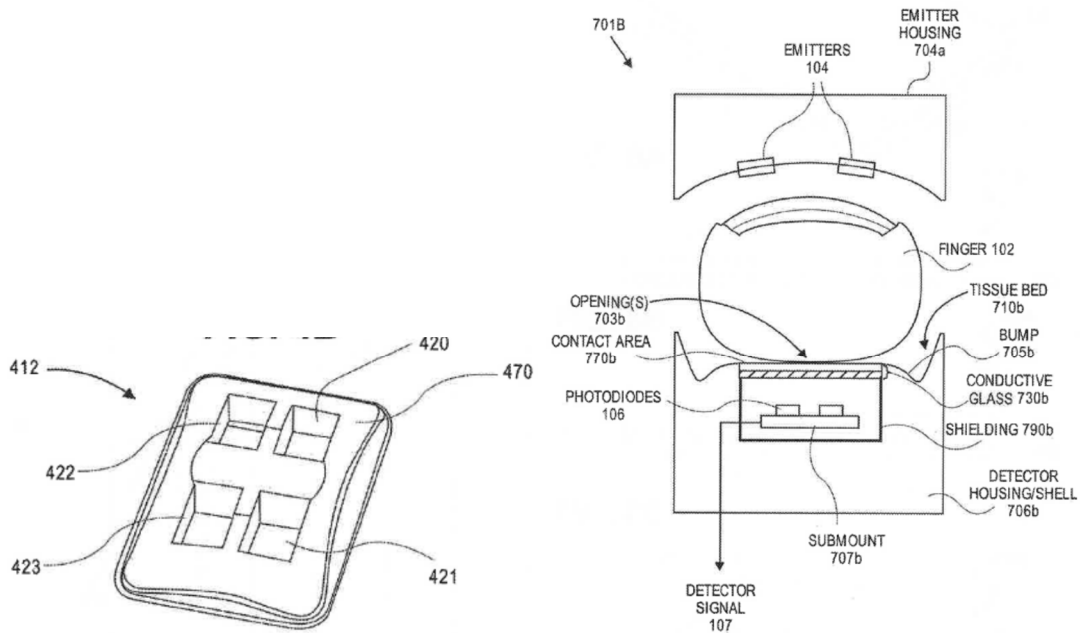


FIG. 4C

FIG. 7B

JX-0001 Figs. 3C, 4C, 7B

Complainants also lean on Figures 7A and 8B—a single-opening embodiment that, as discussed further below, has no connection to the claims—and note “the specification describes a

Finally, even in response to Apple's invalidity arguments, Complainants once again reiterate their false copying claim. But as further detailed below, there is not a shred of evidence that Apple copied the Poeze Patent. Complainants' vague reference to Apple "tearing down" their products (CIB 120) relates to a Masimo forehead sensor and finger-clip sensor—*neither* of which is alleged to practice the Poeze Patents—and Apple's use of these products as "reference" devices in 2013 for a *heart rate* sensor. CX-0185C [REDACTED] at 18-21 (benchmarking public Masimo forehead sensor), 27-29 (benchmarking public Masimo finger-clip sensor); Tr. [Land] 961:18-21 [REDACTED] [REDACTED]). This evidence provides absolutely no support for Complainants' serious allegations of copying.

b. Lumidigm Alone Anticipates the Asserted Claims or, at a Minimum, Renders Them Obvious.

At the hearing, Professor Warren testified at length about Lumidigm's disclosures. *See* Tr. [Warren] 1203:17-1229:19. He explained that Lumidigm provided "a collation of what was known about the time" of the Poeze Patents. *Id.* 1204:8-17. He further explained how Lumidigm taught *every* element of the claims, including for its wristwatch embodiment. *Id.* 1207:23-1229:19. Dr. Madisetti's opinions, in contrast, extended only so far as the text on the demonstratives from which he read—nearly verbatim. Dr. Madisetti's testimony was wholly conclusory, without any substantive analysis, and warrants no weight. *cxLoyalty, Inc. v. Maritz Holdings Inc.*, 986 F.3d

1367, 1378 (Fed. Cir. 2021) (“We do not accord weight to conclusory expert testimony.”). Lumidigm plainly discloses every one of the disputed limitations.²⁸

(1) Lumidigm Discloses a User-Worn Device Configured to Calculate, Determine, and Output Measurements of SpO₂ (And Other Physiological Parameters).

Complainants’ contention that Lumidigm makes “no mention” of measuring oxygenation other than “aspirational” functionality is flatly inconsistent with Lumidigm’s express disclosures. Lumidigm unequivocally states that its sensor can “*quantify oxygenation levels*” (RX-0411 at 19:22-28), and a POSITA would have needed no further disclosure to implement this well-known functionality in a watch as it had been known for decades and “was a standard reflectance mode sensor application.” Tr. [Warren] 1216:10-19; *see also* RX-0484 [Herczfeld] at Fig. 1, Abstract (1969 reflectance pulse oximeter for measuring oxygenation).²⁹

Complainants’ suggestion that Lumidigm does not disclose that its wristwatch embodiment can measure oxygenation is equally baseless. Lumidigm expressly confirms that *all* its “devices”—*including* the “watch”—can perform a “hemoglobin-monitor function” and quantify oxygenation. RX-0411 at 3:35-47 (confirming that same “electronic arrangement” can include “functions of . . . a watch” and “spectrometer function” including “hemoglobin monitor” function); *see also* 4:25-29, 10:11-15, 19:8-12, 19:16-28. This functionality, like the other “extended functionalities,” was well known and “a person of ordinary skill would not have needed any

²⁸ Complainants argue that Apple withdrew Lumidigm anticipation for ’502 claim 28. CIB 123 n.10. Complainants, however, acknowledge that Apple presented Lumidigm anticipation for ’502 claim 28 in Apple’s pre-hearing brief and at the hearing. Complainants do not appear to seek any specific relief, but none is available. Complainants’ failure to object at either stage waived any objection.

²⁹ The other functionalities that Complainant attempt to characterize as “aspirational,” such as the fruit ripeness monitor, were also well-known spectrometer functionalities. Tr. [Warren] 1206:9-25.

additional information to make [the pulse oximetry functionality] work in this kind of an embodiment.” Tr. [Warren] 1216:10-19, *see* 1215:18-1216:9.

The suggestion that a POSITA would not have known how to implement Lumidigm’s wristwatch with pulse oximetry functionality, or had a reasonable expectation of success, is also inconsistent with the evidence. Although the wrist has more complications than other measurements sites, Professor Warren’s own *undergraduate* students were building pulse oximeters that could take measurements at the wrist by **2002**, more than six years before the priority date of the Poeze Patents:



RX-0632 [2002 photograph]; RX-0504.0001 [2005 Wareing Poster] (identifying the “[w]rist” as a “[v]iable and [u]nobtrusive [m]easuring [s]ite[.]”); RX-0508.0007 [2005 Warren Article] (identifying “wrist” as location for acquiring signals); Tr. [Warren] 1195:24-1196:10, 1216:10-25.

As referenced above, the challenges Apple faced developing the Blood Oxygen feature for Apple Watch implicated other issues, including accomplishing the functionality in a small yet attractive form factor, loaded with other components. DocID 773735 (substituting Warren Op. ¶ 244 for Tr. [Warren] 1217:11-21); Tr. [Warren] 1243:5-16. Both Professor Warren and his

students took measurements at the wrist prior to 2008, thereby confirming that Apple’s challenges related to other features of its implementation-. Tr. [Warren] 1216:20-25 (“I did it myself in the mid-‘90s, and then when I started at Kansas State my own students built these sensors and worked with them on their wrists.”).

(2) Lumidigm Discloses Photodiodes.

Complainants’ contention that Lumidigm does not disclose photodiodes is also untenable. A POSITA would have understood that a detector made of “InGaAs” or “silicon” (RX-0411 at 6:56-63) is a photodiode. Tr. [Warren] 1208:25-1209:17. Indeed, multiple prior art references, including Webster, corroborate this. RX-0035.0053 (“The photodetector is a silicon photodiode that produces current linearly proportional to the intensity of light striking it.”); RX-0035.0091 (“[M]ost pulse oximeters currently use silicon photodiodes.”); RX-1221.00001 (identifying “silicon NPN planar epitaxial phototransistors”). Dr. Madiseti’s testimony that Lumidigm “has no photodiodes disclosed” is entirely conclusory, lacks any analysis, and should be disregarded. Tr. [Madiseti] 1329:25-1330:2, 1341:21-25; *cxLoyalty*, 986 F.3d at 1378.

(3) Lumidigm Discloses a Protrusion Comprising a Convex Surface.

Complainants try to avoid Lumidigm’s clear teaching of a protrusion with a convex surface by suggesting that “sensor surface 39” is not the “optical surface” of the sensor. CIB 130-131. But these are the same—“sensor surface 39” is the surface between the optical components emitting and receiving light and the tissue attenuating the light (and is thus the optical surface), and Lumidigm expressly states that a purpose of the convex protrusion is to provide “good optical and mechanical coupling with the tissue being measured” (further confirming that the optical surface with the compound curvature would be the one emitting and receiving light and touching the skin). Tr. [Warren] 1205:20-1206:7, 1210:13-1211:8, 1233:1-14; RX-0411 at Fig. 2, 7:57-63.

Moreover, Lumidigm further explains that the sensor may incorporate “an optical relay (not shown) between the sensor surface 39 and the skin 40,” that this optical relay “transfers the light from the light sources to the skin and from the skin back to the detector(s),” and that it “can be contoured to fit specific product applications and ergonomic requirements.” RX-0411 at 8:19-28. This disclosure further confirms that sensor surface 39 is the optical surface and that it can be “contoured,” consistent with the earlier disclosure that the optical surface can have a compound curvature. *Id.*

Complainants’ further arguments are equally baseless. Dr. Rowe did **not** testify that the compound curvature would be concave. CIB 132. To the contrary, he said that it would match the surface of the skin, so that the **convex** protrusion would conform **tissue** into a concave shape. CX-0279C [Rowe Dep.] 133:21-135:03, 135:06-136:12. The portion of his testimony Complainants cite (69:8-21) says **nothing** about a concave protrusion.

Complainants’ suggestion that a POSITA would not recognize the “compound curvature” as one of the “geometries” that could be included in Lumidigm’s wristwatch embodiment, and would not be motivated to include it, is equally unfounded. CIB 132. A compound curvature is, by definition, a geometry, and Lumidigm expressly teaches in **multiple** places that it can be used with any of Lumidigm’s embodiments, including the wristwatch. *See, e.g.*, RX-0411 at 10:42-49, 11:60-12:2. And sensors with convex protrusions have been known for 50 years and have the known benefit of “push[ing] residual blood out of the way and increas[ing] your AC-to-DC signal ratio, meaning that you would see the tissue perfusion in a better way.” Tr. [Warren] 1194:17-1195:5, 1195:20-22, 1233:1-14. A POSITA would, at a bare minimum, have found it obvious to include the compound curvature in Lumidigm’s wristwatch.

There is also no basis for Complainants' contention that the prior art "taught away" from using a protrusion with a convex surface. **First**, Mendelson does not address a convex protrusion **at all** and instead discusses the problems that arise from uneven contact pressure between the sensor and the user's skin. Tr. [Warren] 1244:11-1245:7; RX-0668 at 2:47-57, 3:45-52, 4:59-65. There was no skepticism in the field regarding the use of convex protrusions; instead, their use and benefits were well known, as Lumidigm, Nippon, Seiko 131, and Cramer corroborate. Tr. [Warren] 1244:11-1246:12; RX-0411 at 7:57-63, 8:27-28; RX-0666 at 3:22-28, 19:5-8, Fig. 28; RX-0670 at 5:45-51, Figs 3, 6, RX-0665 at 2:57-62, 5:12-17, Fig. 3b.

Second, Complainants' contention that a POSITA would not add a convex protrusion to a wristwatch not only distorts Dr. Rowe's testimony (as discussed above) but also ignores that others did exactly that (including Seiko 131 and Cramer). A POSITA would have recognized the benefits of doing so including pushing residual blood out of the way to increase the signal-to-noise ratio, thereby increasing signal strength and quality, all while minimizing user discomfort. Tr. [Warren] 1194:17-1195:5, 1210:13-1211:8, 1232:10-20, 1245:8-1246:12; RX-0666 at 3:7-17, 3:22-28, 17:55-18:2, 24:49-65, Figs. 21A-21B (confirming same).

Third, Complainants contend that adding a protrusion to Lumidigm's watch would add to the form factor. But as Lumidigm teaches, there are also benefits to the curvature. RX-0411 at 7:57-63, 8:27-28. And while Apple's design goal was [REDACTED] while adding hardware, Apple was able to accomplish this [REDACTED] Tr. [Block] 899:21-900:12; Tr. [Land] 959:14-960:2. Accordingly, even if Apple's design choices were relevant to invalidity (which they are not), Apple Watch's [REDACTED]

Finally, Complainants’ suggestion that Apple provided no analysis of expectation of success is incorrect. As Apple explained in its initial post-hearing brief and Professor Warren attested to at the hearing, a POSITA would have expected success in including the convex protrusion in Lumidigm’s wristwatch for multiple reasons—Lumidigm expressly suggests doing so, and a POSITA would have known this had been done many times before. RIB 74-75; Tr. [Warren] 1232:10-1233:14; RX-0411 at 7:57-63, 8:27-28; *see also* RX-0666; RX-0670. As further discussed in the next section, a POSITA would have similarly expected success in combining Lumidigm with Seiko 131’s or Cramer’s protrusion.

(4) Lumidigm Discloses a Protrusion Over/Above an Interior Surface.

Complainants’ argument that Lumidigm fails to teach a protrusion over/above the interior surface holding the photodiodes is equally unfounded. Lumidigm’s Figure 2, an exemplary cross-section of Figure 1, illustrates a protrusion extending over and above the interior surface holding the photodiodes:

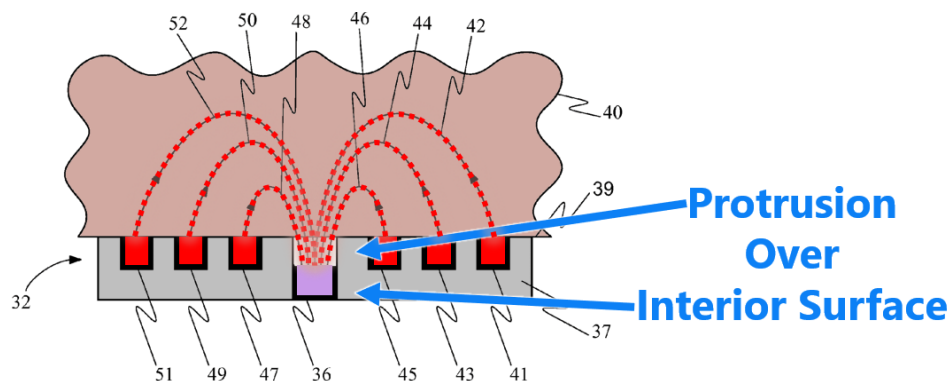


FIG. 2

RX-0411 at Fig. 2; Tr. [Warren] 1209:19-1211:8. Lumidigm further explains that the photodiodes are “recessed from the sensor surface 39” (i.e., that there is a protrusion over the interior surface holding them). RX-0411 at 8:1-4.

Dr. Madisetti's testimony that Lumidigm "has no protrusion at all or over an interior surface" is, once again, conclusory, lacks analysis, and should not be credited. Tr. [Madisetti] 1329:24-25; *cxLoyalty*, 986 F.3d at 1378. Complainants' further contention that Lumidigm has no "singular" interior surface holding both the LEDs and photodiodes is a complete red herring. The Poeze embodiments also have no such "singular" surface, and the claims require none (they refer only to the interior surface holding the photodiodes).

(5) Lumidigm Discloses "Openings" and "Through Holes" in the Protrusion and Windows in the Openings.

Complainants do not dispute that Lumidigm has openings/through holes over the photodiodes, nor could they. Lumidigm plainly discloses these in its figures:

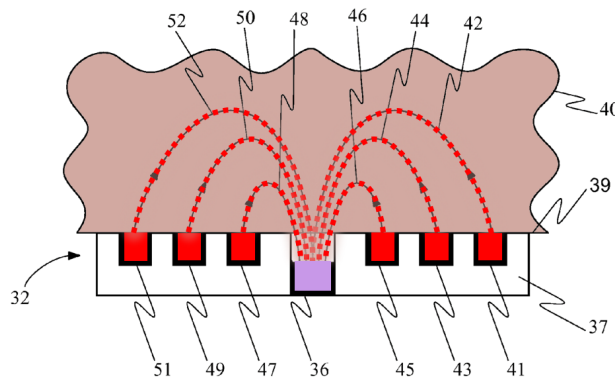


FIG. 2

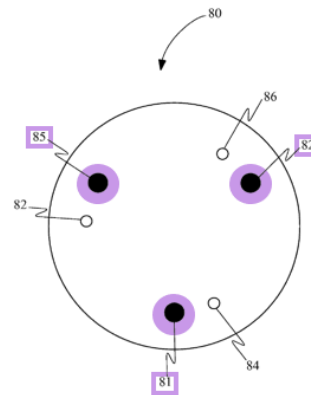


FIG. 6

RX-0411 at Figs. 2 and 6; Tr. [Warren] 1211:10-1212:10, *see* 1192:25-1193:6, 1195:16-19.

Complainants' contention that Lumidigm lacks windows/optically transparent material is incorrect. Although Lumidigm does not *show* "optical relays" or windows over the openings in a figure, it explicitly *discloses* them in the specification. RX-0411 at 8:19-26. Complainants also argue that Lumidigm does not disclose a lens, but Professor Warren's testimony was simply that a POSITA would understand Lumidigm's disclosure of an "optical relay" as "a lens," a point not disputed by Dr. Madisetti. Tr. [Warren] 1222:1-2. Professor Warren further confirmed that

Lumidigm’s explicit examples of such optical relays, including the “fiber optic face plate” and “fiber bundle,” would meet the claim limitations. Tr. [Warren] 1221:16-1222:25, 1235:14-1236:2.

Dr. Madisetti’s testimony, once again, is conclusory, lacks analysis, and entitled to no weight. Tr. [Madisetti] 1330:2-3, 1343:1-3; *cxLoyalty*, 986 F.3d at 1378.

(6) Lumidigm Discloses Opaque Lateral Surfaces and Opaque Materials Configured to Avoid or Reduce Light Piping.

Complainants’ argument that Lumidigm has no opaque lateral surfaces or opaque material configured to avoid or reduce light piping is also baseless. Lumidigm expressly discloses the same use of opaque materials as the Poeze Patents for the same purpose. RX-0411 at 8:1-11 (describing recessing detectors in “optically opaque material” for “optical blocking”); Tr. [Warren] 1212:11-1213:3.

Complainants argue that the Poeze Patents also describe other means for addressing light piping, such as a noise shield. But even if true, *none* of those other means is relevant to the claims. Instead, the claims focus *solely* on the use of openings with opaque surfaces or materials to reduce light piping. Lumidigm uses exactly the same technique.

Dr. Madisetti’s testimony as to these teachings in Lumidigm is again conclusory and cannot be credited. Tr. [Madisetti] 1330:9-12, 1342:15-22; *cxLoyalty*, 986 F.3d at 1378.

(7) Lumidigm Discloses a Thermistor and Adjustments Responsive to Temperature

Lumidigm not only discloses performing corrections for temperature, but also expressly states that techniques for doing so are “well known in the art.” RX-0411 at 14:21-29. Professor Warren confirmed that a POSITA would have readily understood this to include a thermistor and processors for adjusting operation based upon temperature signals. Tr. [Warren] 1223:1-20, 1238:15-23; *see Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337-38 (Fed. Cir. 2020)

(affirming obviousness based upon a POSITA's general knowledge). Dr. Madisetti testified only that Lumidigm "has no thermistor, no adjustment responsive to temperature," and did not even attempt to dispute that both were well known in the art for performing temperature corrections. Tr. [Madisetti] 1330:13-15, 1343:12-17.

(8) Lumidigm Discloses All Remaining Limitations.

Complainants additionally contend that Lumidigm fails to teach a hodge-podge of other limitations, such as cavities, a network interface, a touch-screen, memory, and chamfered edges. CIB 141-43. But as Professor Warren explained and Apple confirmed in its initial post-hearing brief, Lumidigm teaches all these. *See, e.g.*, Tr. [Warren] 1226:2-1227:14, 1228:24-1229:10; RX-0411 at 7:57-63, 8:1-11, 11:38-42, 12:66-13:14, 19:22-28, Figs. 2, 8B, 8D-8E, 9; RIB 93-97, 102-03. Dr. Madisetti barely touched these limitations in his testimony and did not even attempt to substantively explain why these limitations were not met. His testimony is entitled no weight. Tr. [Madisetti] 1330:8-9, 1343:8-11, 1343:12-17; *cxLoyalty*, 986 F.3d at 1378.

c. Alternatively, the Lumidigm Combinations Also Invalidate the Claims.

Apple is not attempting to "bridge" any purported "gaps" in Lumidigm by proposing obviousness combinations, as Complainants suggest. CIB 122. Instead, Apple and Professor Warren's proposed combinations simply demonstrate that the features **Complainants** contend are missing from Lumidigm were well known and had been disclosed, many times over, including in Seiko 131, Cramer, Webster, and Apple '047.

Complainants' suggestion that the Patent Office considered Seiko 131, Cramer, and Webster grossly distorts the prosecution history. Complainants filed the applications for each of the three Poeze Patents with a single, identical claim having two limitations and, along with each application, submitted a "Track One" request to complete prosecution within 12 months. JX-0004

[’501 History] at 3, 101; JX-0005 [’502 History] 3, 101; JX-0006 [’648 History] 3, 101. After the Patent Office granted the expedited examinations for the ’501 and ’502 patents (with the ’648 patent’s Track One request being granted days later), Complainants canceled the original three claims, added over **30** new claims per application, and identified **over 2,000** prior art references per application. JX-0004 at 200 (granting expedited prosecution), 201-67 (IDS), 271-80 (IDS), 298-303 (amending claims), 306-08 (IDS), 313-14 (IDS), 319-22 (IDS), 330 (IDS), 357 (IDS), 374 (IDS); JX-0005 at 200, 201-67, 271-80, 298-303, 305-07, 312-13, 318-21, 329, 345, 353; JX-0006 at 201-78, 296-300, 303-06, 311-12, 317-20, 328, 344, 352. The claims issued only two and a half months after filing. JX-0004 at 24, 379; JX-0005 at 24, 379; JX-0006 at 24, 377. Thus, there is no basis for the suggestion that the Examiner would have found and meaningfully considered Seiko 131, Cramer, or Webster in the identified prior art. Moreover, Apple’s primary reference, Lumidigm, was not identified during prosecution, such that none of the following combinations could have been considered by the Examiner.

(1) Combinations with Cramer and Seiko 131 (All Claims)

Complainants argue that Cramer and Seiko 131 lack the features for which Apple cites them. But Complainants’ arguments are inconsistent with the express disclosures in these references. For example, Complainants focus on the fact that Cramer’s protrusion includes annular rings around a flat surface with openings in between the rings. But that is highly similar to the structure to which Complainants point in the Poeze Patents—Figures 4 and 7 of the patents both show flat center surfaces, with openings, surrounded by convex outer surfaces. JX-0001 at Figs. 4, 7. The asserted claims simply require a protrusion “with **a** convex surface” arranged over the interior surface and photodiodes, **not** one that is wholly convex, and Cramer discloses this. RIB 104-07. Cramer also discloses openings over each of the photodiodes, surrounded by two layers

of opaque surfaces, and including two layers of windows. RIB 107-13. Cramer further discloses chamfered edges virtually identical to those Complainants have accused of infringement in Apple Watch. RIB 114-15.

Complainants do not dispute that Seiko 131 discloses a convex protrusion over an interior surface and photodiode, with an opening and a window over the photodiode. Complainants instead focus on the fact that there is only one photodiode, and therefore only one opening and one window for that photodiode, but a POSITA would have readily recognized that, in sensors with multiple photodiodes, there would be similar openings and windows for each of the photodiodes. RIB 107-13; Tr. [Warren] 1211:10-1212:10, 1221:16-1222:9, 1225:16-1226:1.

Complainants further argue that Seiko 131 fails to disclose opaque lateral surfaces or materials within the openings to avoid/reduce light piping, but Seiko 131's figures show these:

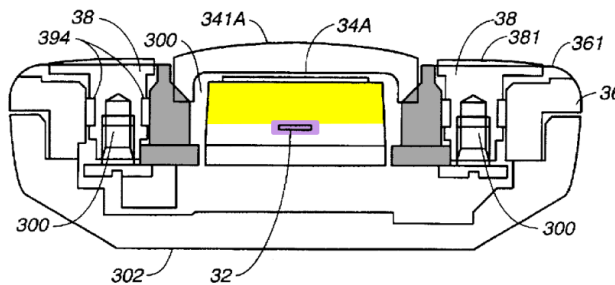


FIG. 28

RX-0666 at Fig. 28; Tr. [Warren] 1233:15-1234:2. Complainants also argue that Figure 28 of Seiko 131 does not have a protrusion with chamfered edges, but Complainants do not dispute that Figure 5 provides such a disclosure. RIB 114-15.

Complainants contend that a POSITA would not have been motivated to make the combination of Lumidigm with Seiko 131 and Cramer or had a reasonable expectation of success in doing so. But Lumidigm *expressly suggests every one* of these combinations. See, e.g., RX-0411 at 7:57-63 (protrusion with convex surface and chamfered edges), 8:1-11 (openings with

opaque surfaces), 8:19-26 (windows/transparent materials), Figs. 2, 6, 8B; RIB 106-07, 110-11, 113, 115-120. Even apart from Lumidigm's teachings, a POSITA would have been *independently* motivated to make the combinations, and had a reasonable expectation of success, because the benefits of the features were well-known in the art and taught in multiple other references, including Seiko 131 and Cramer themselves. RIB 106-07, 110-11, 113, 115-120. Complainants' arguments to the contrary are flatly inconsistent with the evidence and ignore Lumidigm's, Seiko 131's, and Cramer's express teachings. For example:

- Although Cramer recognizes the potential for discomfort if the *strap* is too tight, RX-0670 at 5:26-31, it explicitly confirms that its convex surfaces "insure both comfortable wearing and sufficient contact" for accurate measurements and "minimum discomfort." *Id.* at 5:20-25, 5:45-51. Lumidigm and Seiko 131 similarly recognize that a convex surface can *increase* comfort. RX-0411 at 7:58-63, 8:27-28; RX-0666 at 3:7-17, 3:22-28, 18:51-44. Complainants argue the comfortable design in Cramer is due to the "coaxial arrangement" of the bosses, but it is the convexity of the boss area that provides the comfort. Tr. [Warren] 1231:15-22, 1232:21-25, 1245:17-1246:12; RX-0670 at Fig. 3.
- Seiko 131 and Cramer both describe their protrusions as "improving" contact. RX-0666 at 3:22-28, 19:5-8, Fig. 28; RX-0670 at 5:45-51, Figs. 3, 6. A POSITA would have understood that improving contact improves signal quality. Tr. [Warren] 1194:17-1195:5, 1210:13-1211:8, 1232:10-20, 1245:8-1246:12; RX-0666 at 3:7-17, 3:22-28, 17:55-18:2, 24:49-65, Figs. 21A-21B (confirming same). As discussed above, Mendelson does not teach away from such contact.
- Professor Warren did not argue only that a POSITA "could" make the combinations. He explicitly confirmed not only that they "would" to do so, but also that many others had made similar combinations. *See, e.g.,* Tr. [Warren] 1237:4-16, 1238:1-6, 1241:14-17, 1242:6-9.

Moreover, all of these references are directed to wrist-worn sensors, and a POSITA would have readily understood that the concepts in Seiko 131 and Cramer could be combined with Lumidigm with a reasonable expectation of success. RIB 106-07, 110-11, 113, 115-120.

(2) Combinations Adding Webster for 502 Claim 22

As Apple demonstrated, it would have been obvious to add Webster to Lumidigm alone, or to the Lumidigm/Seiko 131/Cramer combination.

Complainants concede that Webster discloses a thermistor and processors that adjust operations based upon temperature signals from the thermistor. Complainants attempt to distinguish Webster's disclosures but fully ignore how a POSITA would have understood Webster's teachings in the context of Lumidigm. Lumidigm expressly recognizes that components for making temperature adjustments are "well known in the art." RX-0411 at 14:21-29, Fig. 9. Complainants cannot reasonably dispute that a thermistors and associated processors, such as those disclosed in Webster, were well known in the art, especially in the context of pulse oximetry when Webster is titled "Design of Pulse Oximeters." RX-0035.00001.

Moreover, Complainants attempt to distinguish Webster's sensor with a thermistor, but those distinctions are beside the point. Apple is combining Webster's *thermistor* with Lumidigm's *sensor*, not with Webster's sensor. Lumidigm expressly recognizes that components for making temperature adjustments are "well known in the art," and that they can be combined with *Lumidigm's* sensor. RX-0411 at 14:21-29, Fig. 9. Complainants cannot dispute that thermistors, such as disclosed in Webster, were well known in the art.

Finally, Complainants offer no separate arguments against the larger combination of Lumidigm/Seiko 131/Cramer/Webster. As Professor Warren confirmed, this larger combination would have been obvious for the same reasons. RIB 126-28.

(3) Combinations Adding Apple '047 for '502 Claim 28

As Apple demonstrated, it would have been obvious to add Webster to either the Lumidigm/Webster combination, or to the Lumidigm/Seiko 131/Cramer/Webster combination. RIB 126-128.

Complainants do not dispute Apple '047's disclosure of a touchscreen or their prevalence at the time of the Poeze Patents, including as part of the iPhone. Complainants contend that a POSITA would not have looked to Apple '047 for a blood oxygen display, but a POSITA would have understood that display technology is scalable and would have sought to introduce a touchscreen into Lumidigm's wristwatch embodiment to improve the user experience and reduce costs. RIB 132-35. The embodiments in Lumidigm disclose displaying information, which would include physiological measurements (e.g., RX-0411 at Figs. 8B-8E, 3:35-37, 21:29-36), and a POSITA would have sought to improve the display using a touchscreen to display physiological measurements. RIB 132-35. Lumidigm expressly suggests the inclusion of a touchscreen and a POSITA would have independently known the existence of touchscreens for small electronics and would have looked to prior art like Apple '047 for guidance. *Id.*

Finally, Complainants once again offer no separate arguments against the larger combination of Lumidigm/Seiko 131/Cramer/Webster/Apple 047. As Professor Warren confirmed, this larger combination would have been obvious for the same reasons. RIB 137-40.

(4) Kansas State Grounds

Apple continues to believe that the K-State 6D grounds also render the claims obvious. Those arguments, however, were not presented at the hearing solely because of time constraints.